

1 UNITED STATES FOOD AND DRUG ADMINISTRATION
2 CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

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8 Virtual Public Meeting on Patient-Focused Drug
9 Development for Long COVID

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16 DATE: Tuesday, April 25, 2023

17 TIME: 10:00 a.m.

18 LOCATION: Remote Proceeding

19 U.S. Food and Drug Administration

20 White Oak Campus, Building 31

21 10903 New Hampshire Avenue

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23 JOB No.: 3406507

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1 P R O C E E D I N G S

2 WELCOME

3 MS. BENT: Good morning. Thank you all for
4 joining us today for our patient-focused drug
5 development meeting for long COVID. I'm Robyn Bent, the
6 director of patient-focused drug development within the
7 Center for Drug Evaluation and Research at the FDA. I
8 will serve as a discussion facilitator for today's
9 meeting.

10 We have a full agenda planned for the meeting
11 today. We'll start with hearing opening remarks from
12 Admiral Rachel Levine. After Admiral Levine's opening
13 remarks, we'll hear from Dr. Theresa Mullin, associate
14 center director for strategic initiatives in the Center
15 for Drugs, who will talk about FDA's patient-focused
16 drug development efforts.

17 We'll then spend some time hearing from Dr.
18 Hilary Marston, the chief medical officer of the FDA,
19 who will provide us with a background on long COVID just
20 to set the stage for the meeting.

21 We'll then move into our discussion with
22 individuals who are living with long COVID and their
23 loved ones and advocates. We have three sessions. Our
24 first session will focus on the health effects and daily
25 impacts of long COVID that matter most to individuals.

1 Our second session will focus on your thoughts about
2 current approaches to managing long COVID. And our
3 third session will focus on considerations when choosing
4 whether or not to participate in a clinical trial, what
5 are some of the things that make participation easier
6 and what might make it harder. I'll better explain the
7 meeting format and process right before we get into our
8 first panel session.

9 Before we begin, I'd like to go over a few
10 logistic and housekeeping points. This meeting is
11 taking place in a fully virtual setting and is focused
12 on hearing from people who have personal experiences
13 with long COVID. Throughout the day, we'll have polling
14 questions. You'll be able to answer those polling
15 questions using a cell phone or any type of computer or
16 tablet. We'll talk a bit more about that in a few
17 minutes. In addition to the polling questions, you'll
18 have the opportunity to share your experiences by either
19 using the chat feature in the bottom right corner of the
20 meeting screen or by calling the phone number that we'll
21 be putting up on the screen throughout the meeting.

22 As I mentioned, we'll be taking calls
23 throughout the meeting from people with personal
24 experiences with long COVID. We're set up to take calls
25 and receive comments in both English and in Spanish, so

1 please share your experiences in either language.

2 One request that we have is that since the
3 interpreters are simultaneously translating the meeting,
4 if you do call in to speak with us, please try to speak
5 slowly and clearly so the interpreters are able to
6 effectively translate English to Spanish and Spanish to
7 English. If we set things up correctly, you'll not hear
8 the translation while you're speaking. This meeting is
9 being webcast in both English and in Spanish.
10 Captioning is available in both languages as well. The
11 live webcast is being recorded. Both the webcast and
12 transcripts of today's meetings will be archived on our
13 website.

14 And with that, it is my pleasure to introduce
15 Dr. Admiral Rachel Levine who will provide our opening
16 remarks for the meeting. Admiral Levine serves as the
17 17th assistant secretary for health for the U.S.
18 Department of Health and Human Services and is the head
19 of the U.S. Public Health Service Commissioned Corps.
20 She fights every day to improve the health and wellbeing
21 of all Americans. She's working to help our nation
22 overcome the COVID-19 pandemic and build a stronger
23 foundation for a healthier future, one in which every
24 American can attain their full health potential.

25 Admiral Levine's storied career first as a

1 physician in academic medicine, focusing on the
2 intersection between mental and physical health,
3 treating children, adolescents and young adults and then
4 as Pennsylvania's physician general and later as
5 Pennsylvania's secretary of health. She addressed
6 COVID-19, the opioid crisis, behavioral health and other
7 public health challenges.

8 Admiral Levine, I invite you to turn on your
9 camera and unmute your microphone, ma'am.

10 OPENING REMARKS

11 DR. LEVINE: Well, thank you very much. Good
12 morning, and thank you for that kind invitation. And
13 I'm very pleased to be with you today. It is truly my
14 honor to hear from people with long COVID, their
15 advocates and those that care for them. So thank you
16 for the FDA for hosting this meeting.

17 In April of 2022, President Biden issued a
18 memorandum and fact sheet accelerating the whole of
19 government efforts to prevent, detect and treat long
20 COVID, and he tasked HHS with hearing the charge. We
21 convened our federal partners through the long COVID
22 Coordination Council to facilitate this work, and we
23 released two reports.

24 The first was the "Services and Supports for
25 Longer Term Impacts of COVID-19" report. This is a plan

1 that outlines over 200 federally funded supports and
2 services for individuals experiencing long COVID and
3 associated conditions and also mental health substance
4 use issues and bereavement.

5 The second report was the "National Research
6 Action Plan on long COVID," a plan that lays the
7 groundwork for a comprehensive and equitable research
8 strategy to inform our national response.

9 Since the publication of the reports in August
10 2022, we have continued to work with federal partners,
11 including agencies such as the FDA. Most people who
12 have COVID-19 recover quickly and completely. But some
13 people continue to experience new, persistent and
14 reoccurring symptoms or conditions for weeks, months or
15 even years after the initial infection, and this has
16 been termed long COVID. I think everyone here today is
17 familiar with this concept of long COVID and have been
18 drawn to this forum to share the ways in which long
19 COVID has impacted their lives, whether as a patient, a
20 provider, a researcher or an innovator. So thank you
21 for being here today and thank you sincerely for helping
22 us better understand what long COVID is and how we can
23 help people.

24 Our driving focus is to ensure that everyone
25 knows that long COVID is real. I'm going to repeat that

1 one. Our driving focus is to ensure that everyone knows
2 that long COVID is real. We want to help people
3 recognize that if they have long COVID and they have the
4 symptoms, that they should get care and support for
5 their symptoms and their condition as soon as possible.

6 Earlier this month, we issued an updated fact
7 sheet that detailed the progress that has been made
8 towards the goals to prevent, detect and treat long
9 COVID. In acknowledgment of the continued need for
10 resources and supports, I visited Children's National
11 Hospital Medical Center, and I visited their post-COVID
12 conditions clinic in DC, where I heard from patients, I
13 heard from children, from their families and their
14 providers about the work that they're doing and the work
15 yet to be done.

16 In the last year, I have traveled across the
17 United States, stopping in cities such as New Haven,
18 Kansas City and Richmond to bear witness to the impact
19 of long COVID on individuals and their families, as well
20 as the health care systems that seek to care for them.
21 People living with long COVID, their families, their
22 healthcare workers and researchers have shared with me
23 the barriers in accessing treatment, from the barrier of
24 providers that people have seen who don't believe that
25 long COVID is real. Other barriers include long wait

1 times for specialist appointments and the lack of
2 treatment options for the variety of symptoms that
3 people have. People I have seen and their families and
4 their providers have implored us to do more and to start
5 translating research into therapeutics so people can get
6 the help that they need as soon as possible, to provide
7 pathways to remission of symptoms and a pathway to
8 recovery.

9 Providers have shown us that they do see
10 patients improve. It's a very important point, always
11 important to have hope, but it does take time.
12 Foundational research is already providing valuable
13 insights in informing the development of long COVID
14 clinical trials. These clinical trials will help find
15 the treatments that you need to help relieve the most
16 challenging symptoms that people have. These clinical
17 trials will test more than a dozen potential treatments.
18 It is critical even in this moment, though, that knowing
19 that you need help today, we need to listen to you. And
20 we want to listen to you today. We want to learn from
21 you, from your caregivers and from healthcare workers
22 and all of those with lived experience.

23 Today, as the FDA hosts us in this virtual
24 public forum, and as significant progress has been made
25 towards the understanding of how to treat long COVID, we

1 want you to help us take a step forward, one more step
2 forward. We want to understand the symptoms that most
3 impact your life, how you're treating them, what factors
4 would you consider when determining whether you would
5 participate in a clinical trial. And through this
6 collaboration with you, we recommit to addressing the
7 longer term impacts of the worst public health crisis
8 that the world has seen in a century and to accelerate
9 understanding and breakthroughs and to do that together,
10 to do that as a partnership.

11 Beyond the winding down of the public health
12 emergency for COVID-19, HHS will continue to address the
13 needs of the long COVID community and continue to
14 partner with patients, with states, industry, with
15 advocates, with academic medical centers and more to
16 ensure our commitment to protecting public health and
17 wellbeing.

18 In the past year, we have made significant
19 progress in the fight against long COVID through
20 developing supports and services, through the research
21 being done at the NIH, the CDC, the VA and more, we have
22 made progress. But we are certainly not done yet.
23 Agencies across the U.S. government continue to work
24 together to conduct research to draw on the lived
25 experiences of those with long COVID and of those who

1 care for them and develop more supports and services.
2 We want to provide opportunities to work together to
3 disseminate information and resources, implement and
4 support critical activities and to advance the science
5 like today's FDA patient-focused drug development
6 meeting.

7 So thank you again for hosting me. I
8 appreciate your dedication, I appreciate your commitment
9 and I appreciate your enthusiasm for convening in
10 support of these public health goals. We know that long
11 COVID is real, and events like today's allow us to
12 answer your most urgent calls to action. I look forward
13 to continuing to work with you, and I want you to know
14 that your support is very important to me, Admiral
15 Rachel Levine, the assistant secretary for health. It
16 is very important to our secretary, Secretary Becerra
17 and the work of this department as we all work together
18 to improve the health of all Americans. Thank you.

19 MS. BENT: Thank you, Admiral Levine. Thank
20 you and your office for working so hard with us on this
21 meeting. We really appreciate it, especially given how
22 busy I know you've all been.

23 I'd like now to invite Dr. Theresa Mullin to
24 unmute and turn on her camera to provide us with a
25 little background on the FDA patient-focused drug

1 development program and on these patient-focused drug
2 development meetings.

3 As I mentioned, Dr. Mullin serves as CDER's
4 associate center director for strategic initiatives.
5 She oversees areas of strategic interest to external
6 stakeholders. She was instrumental in the creation of
7 the patient-focused drug development program, and she
8 leads CDER's international work. Dr. Mullin previously
9 served as director of CDER's Office of Strategic
10 Programs. Before joining the Center for Drugs in 2007,
11 Dr. Mullin was assistant commissioner for planning in
12 FDA's Office of the Commissioner.

13 Dr. Mullin, please go ahead.

14 OVERVIEW OF FDA'S PATIENT-FOCUSED DRUG DEVELOPMENT
15 INITIATIVE

16 DR. MULLIN: Thank you, Robyn. Thank you so
17 much for joining us today for this meeting. And as
18 Robyn said, I'm going to provide you with a brief
19 overview on FDA's patient-focused drug development
20 initiative, And this meeting is part of that. And so,
21 next slide, please.

22 So to begin with, what is FDA's role in
23 medical product development and evaluation? Well, FDA
24 has a broad portfolio, and part of our mission is to
25 protect and promote public health by evaluating the

1 safety and effectiveness of new drugs. And while we
2 play a critical role in drug -- oversight of drug
3 development, and that's one part of bringing products to
4 market, FDA does not develop drugs or conduct clinical
5 trials. Instead, our review divisions at FDA, for
6 example, the Division of Neurology, Division of
7 Psychiatry, Cardiorenal, many others, provide regulatory
8 oversight of the drug development process and make
9 decisions based on a review of the evidence that's
10 generated in those studies, and on that basis, decisions
11 about approval of new drugs and guidance to industry
12 related to these matters. Next slide, please.

13 And so what is patient-focused drug
14 development, or PFDD? Well, this is a systematic
15 approach to ensure that patients' experiences and
16 perspectives and their priorities and needs are captured
17 systematically and incorporated into drug development
18 and evaluation. And next slide, please.

19 This is really important to FDA decision-
20 making. Patients are uniquely positioned, as we
21 understand at FDA, to inform our understanding of the
22 clinical context for drug review and regulatory
23 decision-making. And by that I mean, what is the
24 severity of this condition? What is it like to live
25 with the condition and what treatments are available and

1 how well are they working or not working? And prior to
2 setting up this program, PFDD, the only mechanism we
3 really had available to us to gather patient input were
4 the sort of discussions we might have about a specific
5 application in the context of an advisory committee
6 meeting.

7 And only a few patient representative
8 typically speak at those meetings, and there's a
9 screening process, and so we don't really have a good
10 opportunity in those settings to get the input from the
11 full community of people experiencing a particular
12 condition.

13 So these meetings, like the one today, give us
14 a better way to more systematically collect that range
15 of perspectives on the severity of the condition and
16 what it's like and its impact on people's daily lives
17 and their assessment of what's available and how well
18 those treatments are working or not. Next slide,
19 please.

20 So this slide is really meant -- I think that
21 timeline is kind of pale, so you may not be able to see
22 it very well, but this slide is conveying that the
23 project, this effort began about 10 years ago. And in
24 2012, we had our first -- we set up this program. And
25 from 2013 to '17, we really sort of made it a bit of a

1 pilot effort and conducted 24 different meetings in
2 different disease areas.

3 Oh, okay -- and basically this allowed us to -
4 - there was so much interest in these meetings that we
5 wanted to expand our ability to have them. And so we
6 set up an externally led option here. And this is where
7 patient groups lead the effort to set up and plan the
8 meetings. And we assist them and we go to the meetings.
9 We're able to join the meetings. And it's just been
10 extremely valuable to us. Both the ones that FDA leads
11 and the ones that patient groups lead really have given
12 us a lot of important input. Next slide, please.

13 And this slide shows you just the range of
14 conditions that FDA has and the ones that FDA has
15 conducted. And I want you to note that literally 10
16 years ago today, we had our first patient-focused drug
17 development meeting. And that meeting focused on
18 chronic fatigue syndrome and myalgic encephalomyelitis.
19 And that first meeting, we didn't know how it would go.
20 We found it so powerful and it really made us realize
21 how meetings like this can help us really understand.
22 We're hearing directly from patients. And so in
23 addition to the about 30 meetings that we've held, there
24 have been over 80 meetings that have been conducted
25 externally. And so this has really been a valuable

1 opportunity for FDA and to listen and for patients to be
2 able to share their perspective. Next slide, please.

3 Next slide, please.

4 Thank you. So the format of these meetings is
5 sort of a town hall style. We usually begin with an
6 overview provided by one of the FDA doctors on the
7 clinical background and currently available treatments,
8 and that's followed by panel sessions. The first panel,
9 typically we'll have a focus on symptoms and daily
10 impacts that begins with having a sort of panel of
11 patients and caregivers who provide a range of
12 perspectives and share their experiences. And that sort
13 of sets the stage for a broad facilitated discussion
14 where we hear from everyone and we get the opportunity
15 to hear from everyone who's participating in the meeting
16 and wants to share what their experience has been.

17 That's followed by a session kind of similarly
18 structured that looks at treatment options, and again
19 begins with a panel of individuals' perspectives and
20 what they've experienced to set the stage for that
21 broader facilitated discussion. Next slide, please.

22 And so these meetings, each of them are
23 tailored a little bit to the disease and the questions
24 that may be of particular interest to try to understand
25 better how we can develop treatments that are more

1 effective and better for patients and maybe the issues
2 around trials or other aspects of drug development.

3 And we have a wide range of participants, but
4 we want everyone to remember that these meetings are
5 really intended to hear directly from patients and
6 caregivers. And so we're going to ask others to just
7 remain in listening mode through these discussions so we
8 can all benefit from hearing that perspective from
9 patients, caregivers and patient representative.

10 After these meetings, we often have a docket
11 that we'll open to receive further public input and
12 comments, things people may not have been able to share
13 or thought of during the meeting. We'll put that
14 together with what we hear in the meeting and the
15 recordings of the meeting to try to develop a very
16 comprehensive report. We develop these reports called
17 "Voice of the Patient" reports. And in fact, if you
18 were to go to your favorite search engine and check into
19 "Voice of the Patient" or patient-focused, you'll find
20 the repository that we have there. But we want to have
21 that report as a resource for future reference for our
22 reviewers and for drug developers, patient groups and
23 others. And with that, I'll conclude and thank you
24 again for joining us today and look forward to hearing
25 your perspectives today.

1 MS. BENT: Thank you, Dr. Mullin. I think
2 it's clear from the number of people participating in
3 the meeting today that patient-focused drug development
4 and these PFDD meetings really play an important part in
5 incorporating the patient voice into medical product
6 development.

7 And now I'd like to ask Dr. Hilary Marston to
8 turn on her video and, as soon as I finish her
9 introduction, begin her presentation. Dr. Marston
10 trains in internal medicine and global health equity at
11 Brigham and Women's Hospital. Currently, she is the
12 chief medical officer of the FDA. In this role, she
13 serves as the primary clinical advisor to the
14 commissioner and oversees the Office of Clinical Policy
15 and Programs.

16 Before joining the FDA, Dr. Marston was senior
17 advisor for global COVID-19 response on the White House
18 COVID-19 response team. Dr. Marston has also served as
19 the director for medical bio preparedness and response
20 at the U.S. National Security Council and as medical
21 officer and policy advisor for pandemic preparedness,
22 focusing on emergency infectious disease preparedness
23 and response at the National Institute for Allergy and
24 Infectious Diseases at the National Institutes of
25 Health.

1 Dr. Marston, thank you so much for joining us
2 today. Please go ahead.

3 BACKGROUND ON LONG COVID

4 DR. MARSTON: Thank you so much for that kind
5 introduction and thank you for the invitation to --

6 MS. BENT: Dr. Marston, I'm going to ask you
7 to stop for one moment. We are having just a brief
8 issue with the translation.

9 DR. MARSTON: No problem.

10 MS. BENT: Do we have the translation setup
11 handled?

12 INTERPRETER: Confirming the Spanish
13 interpretation has resumed. Thank you.

14 MS. BENT: Excellent. Thank you. Go ahead,
15 Dr. Marston. I apologize for interrupting you.

16 DR. MARSTON: No apologies. That's so
17 important. Thank you. Important to pause for that. So
18 what I would like to do today is talk first about the
19 terms and definitions; Next, go into some of the
20 clinical features of long COVID, some potential causes,
21 what we understand currently about epidemiology, the
22 treatment options and regulatory challenges for drug
23 development. And I think what you'll hear throughout
24 this talk are a couple of emerging themes. Number one
25 is we've learned a tremendous amount about long COVID.

1 But number two is that we have a ways to go in this area
2 and that's why fora like today are so essential to
3 progress in this area. Next slide.

4 So first, long COVID terminology. So long
5 COVID is a patient-created and now widely accepted term.
6 You will hear other terms that are thrown around in this
7 space, but we have really been working to help coalesce
8 towards this term with the leadership of patients. So
9 other terms that you'll hear include post-COVID
10 conditions, post-acute sequelae of SARS-CoV-2 infection,
11 long-term effects of COVID, post-acute COVID syndrome,
12 and more. But long COVID is the one that we're going to
13 use for the purposes of today and indeed across the
14 federal government. Next slide.

15 And this was actually quite intentional on the
16 part of the federal government. So recognizing that
17 patient-created term, the government built on that with
18 a cross-HHS working group that sought to further define
19 long COVID. And what we came up with is defined on this
20 slide here. So I'm not going to read everything here,
21 but the most important thing is that it's broadly
22 defined and includes a wide range of signs and symptoms
23 that continue or develop after initial COVID-19.

24 Importantly, it's likely not one condition,
25 but it represents many overlapping different entities

1 and likely they have different biological causes and
2 that's something we'll go into in a little bit more
3 detail. So this was the proposed definition shown on
4 this slide and this has been a source of some ongoing
5 discussion and indeed our colleagues over at the
6 National Academies are looking at this definition in
7 more detail, hosting a series of workshops. There's a
8 link to those proceedings in the slide. Next slide.

9 So next, some of the clinical features of long
10 COVID. So I said that it includes a range of symptoms.
11 In fact, over 200 different symptoms have been reported.
12 Most commonly they seem to cluster in a set of different
13 areas. So first, brain, ranging from headache to brain
14 fog. But there are also conditions such as stroke.
15 Nose and nasal cavities, so this is one of the initial
16 symptoms that was discovered quite early on when SARS-
17 CoV-2 came to light, the loss of taste or smell and
18 that's something that in some folks tends to persist.
19 Lungs, this cough and ongoing shortness of breath.
20 Heart, pounding heart and variable response to changes
21 in activity. Skin, some people can get different sorts
22 of rashes and bruises. And kidney, there's an increased
23 risk of acute kidney injury, but often some ongoing
24 effects on the kidney function. Next slide.

25 In terms of the possible causes of long COVID,

1 there are a number of theories here and it's important
2 to say that while we're learning quite a bit about long
3 COVID, this is an area that we're continuing to
4 understand. As I mentioned early on, there are likely
5 some overlapping conditions that are encompassed within
6 long COVID. Similarly, there are likely overlapping
7 etiologies, causes that are actually leading to the
8 symptoms that patients are reporting. So those causes
9 likely include autoimmune conditions. Persistence of
10 the virus is a possible cause, ongoing organ damage or
11 results of existing organ damage and microclots. So
12 microclots can exist in the acute condition but then can
13 come up over time. Next slide.

14 In terms of how common that long COVID is, the
15 range of estimates is wide, everywhere from 5 to 30
16 percent. Some reasons why you have such a large range,
17 number one is the different symptoms and conditions
18 being investigated. So it depends on how you ask the
19 question. Similarly, the bounds of time that you use to
20 define long COVID, so some individuals doing surveys are
21 looking at three weeks after initial infection. Some
22 people say many months. So again, that will dictate
23 what you get in your results from a survey, where the
24 study is asking the question, inpatient or outpatient
25 settings, and how symptoms are assessed, whether it is

1 self-report, drawing from an electronic health record
2 database or formal survey.

3 There is a CDC Household Pulse Survey, which
4 has some nice methodology behind it, that came up with
5 an estimate of 6 percent. Worldwide, that estimate is
6 about 65 million individuals globally. So this is,
7 unfortunately, something that's being seen worldwide.
8 Next slide.

9 Factors associated with getting long COVID.
10 So first, a lot of these are similar to the
11 predisposition to getting severe COVID. So, for
12 example, having preexisting health conditions, having
13 severe initial COVID-19 illness, lack of vaccination
14 prior to SARS-CoV-2, there's some good evidence there
15 and people who experience something called multisystem
16 inflammatory syndrome during or after COVID-19. So
17 multisystem inflammatory syndrome is where different
18 parts of the body become inflamed that include many
19 different parts of the body, from the kidneys to the
20 brain, skin and the gastrointestinal organs. And just
21 as it did with initial COVID-19 infection, health
22 disparities are unfortunately rearing their ugly head
23 when it comes to long COVID as well. And that's
24 something we would like to hear more about.

25 Long COVID in children. So just as there are

1 uncertainties about the prevalence of long COVID in
2 adults, although it's quite clear that it is very
3 common, long COVID in children estimates range quite a
4 bit as well. The symptoms and natural history, some
5 overlap with what's seen in adults and some do not. So
6 this is something that certainly merits further
7 research. Sorry. I'm behind. Can you go forward two
8 slides? Thank you. One more. Thank you.

9 So, in terms of treatment options, so there's
10 no FDA approved drugs or authorized treatments for the
11 treatment of long COVID. For most patients, the goal is
12 going to be to optimize their function and their quality
13 of life. So that's why meetings like today are so
14 important, so that we understand what is most important
15 to patients in terms of those measures. Symptom
16 management approaches, therefore, might be very
17 important here. And management is going to change as
18 the evidence emerges. And we hope that that will happen
19 because it means that we're developing new, better
20 approaches. Next slide.

21 There are many challenges, though, when it
22 comes to drug development. So first is that it's a new
23 entity and we're continuing to understand it. That
24 includes just the epidemiology of the disease. So
25 designing studies, it's really important to understand

1 how common that a condition is. Second, again, there's
2 this heterogeneity, this diversity in the symptoms that
3 people are reporting, and it might indeed be multiple
4 overlapping conditions. That makes it, again,
5 challenging to study and understand if your treatment is
6 having an effect. And then the tools for how we assess
7 how a treatment is working, we want to make sure that
8 those tools are accurately reflecting how patients feel,
9 because again, what we want to be developing in
10 treatments are treatments that really impact the
11 symptoms that the patients are seeing. Next slide.

12 And one point that is important to make here
13 is that our colleagues over at the NIH have been funding
14 a series of studies under the Recover initiative that is
15 working to both understand the natural history of
16 disease, but also the effectiveness of interventions.

17 So, in conclusion, long COVID as a post-viral
18 condition can be very severe and disabling, but present
19 with diverse symptoms and symptom clusters and with
20 several potential biological causes, likely multiple
21 overlapping conditions. There are a number of
22 challenges associated with drug development, but FDA is
23 committed to supporting drug development for long COVID
24 along with our federal partners. And in this, it is
25 essential that we have the patient's voice front and

1 center.

2 So to that end, thank you so much for your
3 attendance here today. We really appreciate it, and we
4 look forward to engaging in the discussion today.

5 Thanks.

6 OVERVIEW OF DISCUSSION FORMAT

7 MS. BENT: Thank you, Dr. Marston. I think
8 that this is really helpful for us to have this
9 presentation to set the stage for what we're about to
10 hear from our panelists and meeting attendees who have
11 lived experiences with long COVID.

12 Moving on, I'd like to share with you all a
13 bit more about how the meeting will proceed. It's been
14 truly an honor to work with the panelists that you'll
15 meet in just a moment as we prepared for today's
16 meeting. And thank you to Admiral Levine and Drs.
17 Mullin and Marston for the very informative
18 presentations that give us some context to think about
19 during this next part of the meeting that really is
20 really all yours.

21 If you're new to this area of what FDA does
22 and what patient-focused medical product development is,
23 then I hope that we gave you just a little bit of a
24 background on that and especially some of the key terms
25 and words that we'll be using today.

1 Before we get started on this next part, where
2 those of you with lived experiences with long COVID are
3 really the main participants, I just want to share a
4 little bit of information, kind of an orientation to
5 build on what Dr. Mullin talked about to help you
6 understand the meeting structure and why we've set it up
7 this way, because it's intentional.

8 Those of you who are here representing
9 yourselves or your loved ones with lived experiences
10 with long COVID, you are the experts. And the expertise
11 that you have is what we're all here to hear about
12 today. We've kind of flipped the script, so to speak,
13 on the type of meeting that most of us go to, where you
14 have a lot of medical professionals giving presentations
15 and having discussions while everyone else listens.
16 Today we've reversed that. We've heard some opening
17 remarks from experts in their field, but you are experts
18 in your field. You're the ones who know what long COVID
19 is like to live with.

20 So our goal today as we start this discussion
21 portion of our meeting is to really foster an open
22 dialogue on personal experiences and perspectives on
23 long COVID. Our three main topics for discussion are
24 health effects and daily impacts of long COVID, followed
25 by current approaches to treatment, followed by

1 considerations for clinical trials.

2 We'll start each session with a panel of
3 individuals with long COVID. There are six panelists
4 for our first topic. After hearing from the panelists,
5 we'll broaden the dialogue to include other individuals
6 and family members who are joining us on the webcast.
7 Anyone who's watching the meeting who identifies as a
8 person with long COVID or a family member or loved one
9 is welcome to participate.

10 Aside from panelists, we don't have anyone
11 else identified to speak, so we need you to share your
12 experiences in order for this meeting to be successful.
13 The purpose is to build on the experiences shared by the
14 panel, and I'll ask a number of follow-up questions.
15 Throughout the day, polling will be done via computer or
16 cell phone, and as I mentioned previously, we're taking
17 comments from online through the meeting chat feature
18 and via telephone if you've got something to add.

19 So this is your opportunity to build on the
20 information shared by panelists. So we really hope that
21 you feel kind of the importance of your participation in
22 the meeting today, to have your experiences and
23 priorities heard, not only by the FDA and others in the
24 federal government, but from representatives from
25 medical product developers, researchers, clinicians

1 about long COVID and what you'd like to see happen to
2 help those with long COVID.

3 So please take this opportunity, and we hope
4 that this will be your invitation to participate with us
5 in the discussion. We encourage you to call in via
6 phone to share your comments when speaking. You can
7 remain anonymous. I mean, you don't have to give us
8 your first name you're your last name. You may state
9 your full name if you want. But really mostly what we
10 care about is you're your experience is.

11 When you call in, there are a couple of things
12 that will help us. One is if you stay on the topic that
13 we're discussing, whatever topic we're talking about.
14 If we're talking about symptoms or if we're talking
15 about daily impact, it would be helpful if you could
16 think about the topic and stay as close as possible to
17 that topic. It's also helpful if you can keep your
18 points to about two minutes and focus really on one or
19 two things that are particularly relevant to you so that
20 we can go on to as many people who want to speak as
21 possible.

22 For transparency, we request that at the time
23 of your first comment, you disclose if you are
24 affiliated with an organization that has an interest in
25 long COVID, or if you have significant financial

1 interests in long COVID drug development. If you're
2 submitting comments via the webcast, you can provide
3 whatever name you'd like. Please don't worry about us
4 being overwhelmed by comments. We can handle it. We'll
5 try to summarize them as much as possible. We'll do our
6 best to share the comments we receive via the Web
7 platform. But if we're not able to read all of the
8 comments out loud today, your comments will be
9 incorporated into our final summary report.

10 One thing that is very exciting about our
11 meeting today is that we've had more than 1,400 people
12 registered to participate. Of the people registered,
13 over 850 of you are either people with long COVID or
14 loved ones or patient representatives. Now, we are
15 grateful, very grateful to the long COVID community for
16 their support of this meeting, but we also realize that
17 there may not be enough time for everyone who wants to
18 share their experiences today to do so.

19 As Dr. Mullin mentioned earlier, we have a
20 public docket for this meeting that will be open until
21 June 26th of 2023. We encourage you to share your
22 experiences and expand upon what we discussed today
23 through the public docket. The comments will be
24 incorporated into our summary report as well. Anyone is
25 welcome to comment through the docket, whether you're

1 joining us via the Web on this meeting or whether you
2 know someone who wasn't able to participate today, but
3 you think they have something to contribute. Please
4 encourage them to submit their comments. You'll find a
5 link on the slide here, and we'll also email this link
6 after the meeting to everyone who's registered via the
7 event website. You can submit your comments to the
8 docket as anonymous as well.

9 And I want you to keep in mind that if you do
10 submit to the public docket, that word public is in
11 there for a reason, and this will go onto the website.
12 So please think about how much personally identifying
13 information you want to share. We don't need that
14 information. We care about what your experience is, so
15 please keep that in mind. You can just say anonymous,
16 anonymous, or leave the parts empty when we ask what
17 your name is.

18 There are also just a few ground rules for
19 today's discussion. We're here first and foremost to
20 listen to those with long COVID and their loved ones.
21 We'll try to accommodate all of those who want to speak.
22 We're happy to see a number of people who represent
23 research and medical product development registered for
24 this meeting. We believe that the input we hear today
25 will be important to you as well. We just ask that you

1 stay in listening mode.

2 FDA staff is really here to listen as well.

3 We know that you may have questions about medical
4 product development or drug review. If you have
5 specific questions, we encourage you to share them with
6 us via email. Our contact information is on the meeting
7 website. We'll get back to you with more information
8 following the meeting.

9 As has been described, our discussion today is
10 focused first on the health effects of long COVID and
11 daily impacts, then approaches to managing those health
12 effects and then clinical trial participation. Our
13 discussion may touch upon scientific treatments.
14 However, the discussion of any specific treatments
15 should be done in a way that helps us to understand the
16 broader issues, such as what health effects are being
17 addressed and how that is meaningful to individuals with
18 long COVID and their loved ones.

19 Our discussion is going to focus again on
20 health effects and treatments. We know that this is a
21 very complicated issue and there are many concerns and
22 many questions you have and things that you have to
23 think about when living with long COVID and getting the
24 support you need. All of those are important. However,
25 today we hope to focus on the topics that FDA needs the

1 most input on so that we can best fulfill our role
2 regulating medical products and facilitating medical
3 product development.

4 And so, while you take in this next slide,
5 which outlines how to actively participate in the
6 meeting, I'd like to take the opportunity to ask my FDA
7 and HHS colleagues to turn -- on the panel to turn on
8 their video and introduce themselves. And we'll start
9 with Dr. Karimi Shah.

10 DR. SHAH: Thank you, Robyn. Good morning.
11 My name is Bani Karimi-Shah. I am the deputy director
12 of the Division of Pulmonology, Allergy and Critical
13 Care here at FDA, and I'm very excited to hear what you
14 all have to say during today's meeting.

15 MS. BENT: Thank you. Dr. Senatore?

16 DR. SENATORE: Good morning. My name is Fred
17 Senatore. I'm a lead physician with the division of
18 Cardiology and Nephrology at the FDA. And I'm excited
19 to be here, and I'm looking forward to learning from the
20 patients who've experienced long COVID. Thank you.

21 MS. BENT: Thank you. Dr. Habal?

22 DR. HABAL: Hi. Good morning. My name is
23 Nadia Habal, and I'm an acting clinical team leader in
24 the Division of Rheumatology and Transplant Medicine at
25 the FDA. And I'm also a practicing adult

1 rheumatologist, and I'm looking forward to this meeting.
2 Thank you.

3 MS. BENT: Dr. Sullivan?

4 DR. SULLIVAN: Hi. My name is Shannon
5 Sullivan. I'm an endocrinologist, and I'm a clinical
6 team leader in the Division of General Endocrinology at
7 FDA.

8 MS. BENT: Thank you. Dr. Stabinski?

9 DR. STABINSKI: Hi, my name is Lara Stabinski,
10 and I am a medical officer in the Division of
11 Antivirals. I'm also a practicing infectious disease
12 clinician.

13 MS. BENT: Thank you. Dr. Connolly?

14 DR. CONNELLY: Hi, my name is Mark Connelly.
15 I'm in the Office of Vaccine Research and Review. I'm a
16 medical officer, and I wanted to thank everyone for
17 sharing their experiences.

18 MS. BENT: Thank you. Dr. Weltz?

19 DR. WELTZ: Good morning. My name is Adam
20 Weltz. I'm a board certified general surgeon,
21 practicing clinician, associate professor of surgery in
22 Annapolis, Maryland. I am also a medical officer in
23 CDRH, which is Center for Devices and Radiological
24 Health, a medical officer on the team that reviewed many
25 of the infection controlled devices during the pandemic.

1 Looking forward to hearing your stories today.

2 MS. BENT: Thank you. We also have Dr.
3 Marston. I know I've introduced you, but if you want to
4 briefly just say hello again.

5 DR. MARSTON: Hello. Just glad to be here.
6 Thanks so much.

7 MS. BENT: Thank you. Admiral Iademarco?

8 DR. IADEMARCO: Yes. Good morning. Good
9 afternoon, everyone. I am Michael Iademarco. I am the
10 deputy assistant secretary for health for science and
11 medicine in the Office of the Assistant Secretary for
12 Health with Admiral Levine. And together we're leading
13 the long COVID coordination across 14 federal government
14 departments. And I am a pulmonologist and ICU
15 physician, spending most of my career in public health.

16 MS. BENT: Thank you. Dr. Soake Adams? All
17 right. Dr. Patel?

18 DR. PATEL: Good morning, everyone. My name
19 is Priti Patel. I'm a senior advisor for post-COVID
20 conditions at the Centers for Disease Control and
21 Prevention. I'm an internist by training and really
22 appreciate the opportunity to be here as part of this
23 meeting today.

24 MS. BENT: Great. Thank you all. You are
25 welcome to turn off your video if you would like at this

1 point. So from time to time during our meeting, we will
2 turn back to our FDA panelists to see if they have any
3 follow-up or clarifying questions about what we just
4 heard from our other panelists.

5 I also want to introduce my colleague, Shannon
6 Sparklin, who will be keeping an eye out for comments
7 that come in through the Internet. She will be backed
8 up by Ethan Gabbour. Shannon will be sharing the
9 comments throughout the meeting. She'll also be
10 coordinating with our other colleagues, Lena Marzouk,
11 Will Lou Allen and Steven Ganache, who you'll speak to
12 if you call in to provide comments on the phone.
13 Shannon?

14 MS. SPARKLIN: Good morning. My name is
15 Shannon Sparklin. As Robyn mentioned, I will be
16 reviewing the written comments that we received through
17 the webcast and summarizing them. Thank you.

18 MS. BENT: I see that I muted myself. It's
19 only three years into the pandemic. So we will have
20 some polling questions today, and we're using a third-
21 party application, Mentimeter, to run our polling.
22 Polling on Mentimeter's site, menti.com, is anonymous
23 and can be done via cell phone or on your laptop or
24 tablet. Please note that we're not tracking individual
25 people's answers. We'll only see the responses grouped

1 by option.

2 You can access the Mentimeter poll in two
3 ways. You can use your cell phone camera to view the QR
4 code on this slide, which will take you to the survey,
5 or you can go to www.menti.com and use the digital code
6 on the slide to enter the survey. It sounds like maybe
7 we're having some issues with the Mentimeter, so we will
8 work on that and we will get that going shortly.
9 Unfortunately, the polling is also only available in
10 English, but I will read the polling questions and
11 answers so that they will be translated.

12 And so with that, let's begin with a polling
13 question. I hear that it is working again. So please
14 get your cell phones or computers ready. All right.
15 Question one. We're starting with some basic
16 demographic questions so that you can get familiar with
17 the polling platform. And so the first question is
18 where do you live. Option A, within the Washington, DC
19 metropolitan area, including the Virginia and Maryland
20 suburbs; option B outside of the Washington, DC
21 metropolitan area.

22 And so while you're completing the polling
23 questions, I'm going to share with you one of the
24 challenges of the virtual setting. There is a little
25 bit of a lag between when we speak here on the backend

1 of the meeting and then what is broadcast to the meeting
2 participants. That lag time can be 15 to 30 seconds.
3 So you'll see the answers for polling kind of trickle
4 in. For some questions, you'll have one answer. For
5 others, you may have multiple answers. These polling
6 questions are meant to be a discussion aid for today.
7 They're not a scientific survey.

8 So let's see. All right. It looks like
9 everything is working and we're getting responses. I
10 don't see a lot of challenges with the application. It
11 seems like it's starting to work, and it looks like this
12 is one of the benefits, I think, of having the meeting
13 in a virtual platform. We really do have a large number
14 of participants who are able to join us from outside of
15 the metropolitan DC area. And for that, we're very
16 grateful because really kind of understanding the
17 experiences of people throughout the country and even
18 more broadly throughout the world is really important
19 and helpful.

20 So let's move on to the next question. Next
21 question, are you or a loved one currently experiencing
22 symptoms of long COVID? A, yes; B, no. All right.
23 Once again, it looks like we're getting some good
24 responses, and we are seeing what we would anticipate
25 from our registration, which is that a majority of the

1 people that registered have had personal experiences
2 through their own or their loved ones long COVID. And
3 so from this point on, we'll ask that each polling
4 question be answered only by an individual living with
5 long COVID or someone who is answering on behalf of a
6 loved one with long COVID.

7 So let's move to the next question. Okay.
8 Here we go. What is your age? Remember, if you are
9 answering for a loved one, please answer with their age.
10 The options are A, 0 to 10 years old; B, 10 to 17 years
11 old; C, 18 to 29 years old; D, 30 to 39 years old; E, 40
12 to 49 years old; F, 50 to 59 years old; G, 60 to 69
13 years old; and H, 70 years or older.

14 All right. And we're getting a good number of
15 responses, and it looks like a majority of our
16 participants today are kind of in that 30 to 60 year age
17 range, with most of our participants being -- it's
18 changing, so most of them being 40 to 49 years old, but
19 just slightly over the 30 to 39 years old. And so I
20 think that this is maybe what we were thinking we would
21 see based on the registration as well.

22 So let me now move on to our next question,
23 which is, do you identify as, A, female; B, male; or C,
24 other? All right. So it looks like we have a majority
25 of female participants at the meeting, but it does look

1 like we have a good representation from males as well.
2 So thank you all. It looks like we have a range of
3 people participating today, all age ranges from across
4 the country. And that's really great. That's what we
5 had hoped for.

6 We have just two more questions, and these are
7 going to kind of delve a little bit. We're going to
8 stop asking about demographics and really try to start
9 understanding your experiences with long COVID. So
10 we'll move on to the next question, which is what parts
11 of your body are affected by long COVID? And for this,
12 you can select all that apply, that includes, A, muscles
13 and joints; B, heart; C, lungs; D, brain and nervous
14 system; E, kidneys; F, liver; G, digestive system such
15 as stomach and intestines; H, blood; or I, other, such
16 as mouth, nose, hair, et cetera.

17 Okay. So we're seeing a lot of muscles and
18 joints, brains and nervous system, and a good amount of
19 other. And so it seems like we're seeing our
20 participants today experiencing issues with multiple
21 parts of the body that are affected by long COVID. And
22 so we're going to hear a bit more about people's
23 experiences with long COVID in just a minute. For those
24 of you who have selected other, I would request that you
25 think about calling in a bit later to share what you've

1 experienced.

2 And so finally, thanks everyone. We're going
3 to have just one more question before we move on to our
4 first panel discussion. And that question is which type
5 of healthcare providers are you seeing for your long
6 COVID symptoms? And you can check all that apply. We
7 have, A, primary care provider. This could be an
8 internal medicine provider, a family practice provider.
9 It could be a pediatrician or a pediatric nurse
10 practitioner if you are answering for your child; B,
11 long COVID specialist or clinic; C, medical specialist.
12 This could include specialty care outside of a long
13 COVID clinic. It would include pulmonologists or
14 cardiologists or other specialists; D, chiropractor or
15 complementary healthcare provider; E, other; or F, none
16 of the above.

17 So it looks like we have a number of people
18 really working with their primary care providers as well
19 as medical specialists. And about 18 or 19 percent --
20 oops, it's dropping, 17 percent being seen in long COVID
21 clinics. All right. So thank you all. I think this is
22 really helpful information. It'll be great as we kind
23 of move into our conversations after we hear from our
24 panel.

25 But now we're going to move right into hearing

1 from our panelists. So now, as I mentioned previously,
2 topic one will focus on the health effects and daily
3 impacts of long COVID. And we have six panelists who
4 will start off the session by sharing their experiences.
5 In about 30 minutes, when our panelists are done sharing
6 their experiences, we'll move into the interactive
7 portion of the meeting by asking you about your
8 experiences. If you hear something from our panelists
9 that really resonates with you or if you want to share a
10 bit of your experience, please consider sharing your
11 comments via the Web or closer to the end of the 30-
12 minute period around 11:30 Eastern time. Maybe give us
13 a call to share.

14 You should also know that if you call in and
15 are placed on hold, the hold music will not be music.
16 It will be the English version of this meeting. So you
17 won't miss out hearing from our panelists if you call in
18 to speak. We will ask you to mute the device you are
19 listening to the meeting on just to prevent there from
20 being any audio issues. If you are Spanish-speaking,
21 you may continue to stream the meeting. But we ask that
22 when you are notified that we will be taking your call,
23 you mute the speakers on your device that is playing the
24 meeting.

25 And with that, we're ready to turn to our

1 panelists. I'd like to start by inviting Jill to share
2 her experiences with long COVID. So Jill, if you want
3 to turn on your video, which you have on, and unmute,
4 thank you so much for being here. And really thank you
5 for being our first panelist.

6 TOPIC 1: HEALTH EFFECTS AND DAILY IMPACTS

7 MS. ANDERSON: Thank you, and good morning.
8 My name is Jill Anderson and I would like to speak to
9 you today about my experience with long COVID. I
10 initially became acutely ill with COVID November 7,
11 2022. Shortly after the resolution of my acute illness,
12 I began to notice lingering symptoms and new symptoms
13 that were not present during my acute illness. Today I
14 would like to focus on a few key symptoms out of the
15 many I endured and continue to experience.

16 One of the initial symptoms I noticed was
17 significant brain fog. I was having difficulty
18 concentrating, thinking clearly, and my memory was so
19 impacted that I was legitimately concerned for my
20 cognitive functioning. Simultaneously, my vestibular
21 system was also impacted. I never had vertigo, but
22 suddenly I was constantly dizzy. It felt like my brain
23 was banging around in my skull. I was off-balance. I
24 could be standing, and then all of a sudden I would just
25 lose my balance. I would get up in the middle of the

1 night and take a step out of bed and fall to the floor.
2 It was terrifying how my world was spinning and out of
3 balance, and I could not recall pertinent information or
4 complete sentences when trying to articulate in
5 conversation.

6 Additionally, I was experiencing significant
7 fatigue that was worsened by my brain working overtime
8 to compensate to the changes to my vestibular system and
9 cognitive dysfunction. I also lost my appetite for
10 about three months, and it continues to come and go.
11 This was coupled with repeated bouts of severe IBS
12 flares that cause pain, cramping and bowel irregularity.

13 So far I've lost close to 20 pounds and I
14 weigh about 102 or 103 pounds currently. Prior to
15 COVID, I was training for a 10K and two 5K races. About
16 a month or two after my acute illness, I started
17 noticing my heart rate changing from a very low rate to
18 racing upon standing. This led to a diagnosis of
19 postural orthostatic tachycardia syndrome, or POTS.
20 POTS is an autonomic disorder and symptoms such as
21 exercise intolerance, headaches, fast heartbeat,
22 dizziness, GI issues, shortness of breath and numerous
23 other symptoms are associated.

24 All of these symptoms discussed I continue to
25 experience. However, they significantly ebb and flow,

1 and every day I wake up and I have no idea what kind of
2 day I will have. I work hard to avoid post-exertional
3 malaise or what I refer to as a crash where I'll push
4 myself too hard mentally or physically, and this will
5 exacerbate symptoms and trigger a two-week migraine or a
6 two-week IBS flare, or I'll be too dizzy to leave my
7 couch for days. Other days I'll get glimpses of symptom
8 improvement, but those are limited.

9 All these symptoms continue to have an impact
10 on my current employment. I'm a director of all the
11 emergency and acute behavioral health services for a
12 community services board in Virginia. My programs are
13 responsible for the safety of the community and the
14 individuals we serve. My career requires multitasking,
15 quick thinking and decision-making and the nature of the
16 work is intense and requires sound risk assessment. I'm
17 on call 24/7, 365 and the role requires in-person
18 attendance as well as direct client intervention when
19 necessary.

20 I'm currently on intermittent FMLA, work
21 mostly remote and work a reduced schedule due to my
22 symptoms. I worry if I'm unable to meet my job
23 expectations due to my -- my job expectations due to my
24 cognitive deficits, fatigue, ongoing migraines and GI
25 issues, continued need for remote work, continued

1 crashes, that I could be moved to a different position
2 or lose my job. I've worked in emergency services and
3 crisis work for my entire professional career of 15
4 years, and this job is incredibly important to me. Not
5 being able to keep up with the demands of this job over
6 the past few months has been devastating. Thank you for
7 your time.

8 MS. BENT: Thank you, Jill. Thanks for being
9 the first one to speak and being brave enough to share
10 your experiences with us. There's certainly a lot there
11 and we really appreciate you sharing that. We're now
12 going to turn to Heather-Elizabeth who is going to share
13 some of her experiences with us.

14 Heather-Elizabeth?

15 MS. BROWN: Thank you so much. Good morning,
16 everyone. My name is Heather-Elizabeth Brown. I am a
17 bivocational minister and corporate trainer in Detroit,
18 Michigan. Currently, I serve as a patient
19 representative and committee leader with the Recover
20 initiative with the NIH. I am also a long COVID
21 advocate, COVID survivor and clinical TRIUMPH
22 participant with long COVID research and awareness.

23 I contracted a very severe case of COVID in
24 April of 2020 during the first wave when there was
25 limited information and limited effective interventions.

1 I contracted COVID-induced pneumonia in both of my lungs
2 that resulted in me being placed into a medically
3 induced coma and onto a ventilator for 31 days from
4 April 18th until May 19th of 2020.

5 Although I had many complications during this
6 time, including having a stroke, blood clots and
7 bleeding issues, I did survive by the grace of God. And
8 very quickly after I began developing symptoms of long
9 COVID, things that had not presented themselves in my
10 initial infection and started to present themselves
11 maybe as early as a month or two after I first was
12 discharged from the hospital.

13 My lived experiences with long COVID cannot be
14 overstated or overemphasized. In every area and every
15 facet, my life has been impacted. After my initial
16 hospitalization, I continue to deal with several long
17 COVID-related issues today. The ones that are still
18 very prevalent and that I still struggle with include
19 brain fog, extreme fatigue and residual emotional
20 challenges, including PTSD. And as a long COVID patient
21 and a survivor, I can definitely say that every major
22 system in my body has been affected by long COVID. That
23 includes my nervous system, from my skin to my hair, my
24 reproductive system, digestive, lymphatic, endocrine,
25 any system you can name has pretty much been affected.

1 And long COVID has not only affected my life, but the
2 lives of my family, my friends, my elderly parents and
3 my brother who have had to sacrifice so much to continue
4 to support me during the seemingly never-ending journey.

5 Before COVID I was serving as a chaplain with
6 the Detroit Police Department. I was very active in
7 several ministries in my spiritual community, and I
8 really enjoyed being outside and walking and taking
9 hikes and doing anything active. However, over the past
10 years, there have been several serious long COVID-
11 related complications and symptoms that I have developed
12 that have presented particular challenges when it comes
13 to my health.

14 Over the past three years, I developed COVID-
15 induced diabetes, which necessitated me taking three to
16 four insulin shots every day for almost a year. I was
17 not diabetic before I contracted COVID. I also
18 developed COVID-induced high blood pressure that
19 necessitated at least two different medical leaves of
20 absence from my employer because of the challenges that
21 those faced. I also had blood clotting issues, which
22 did result in blood clots and a stroke, which I
23 mentioned earlier. And after my initial infection, I've
24 struggled with everything from lymphedema, loss of
25 breath support, fatigue, and again, the brain fog.

1 So I have been lucky that in terms of my
2 limitations and the struggles that I have had with long
3 COVID my employer has been incredible and has done as
4 much as can possibly be done in order to create
5 accommodations and opportunities for me, especially
6 during the first two years when I was having
7 appointments and anything from physical therapy to
8 medical or specialist appointments anywhere from three
9 to five times every week.

10 These continuing issues have definitely
11 severely affected my career and my career trajectory.
12 Although I do now work a hybrid schedule and I do have
13 accommodations, I do still face challenges. Brain fog
14 has been one of the notable ones, especially because as
15 a trainer, my entire business is teaching and training
16 and communicating, so having moments of not remembering
17 what I was talking about, as you can see, could be very
18 challenging.

19 Over time, I would say that my long COVID
20 symptoms have ebbed and flowed. Some have lessened and
21 some have persisted. I would say that obviously the
22 major ones, including the diabetes and high blood
23 pressure, have been the most challenging, and I have
24 seen steady improvement. However, other issues, such as
25 the brain fog have necessitated that I have had to seek

1 out different treatment options in a variety of ways,
2 whether it's with the University of Michigan Long COVID
3 Clinic. I had a complete neuropsychological evaluation,
4 brain scans, MRIs, appointments with different
5 neurologists and specialists, and I've tried traditional
6 and nontraditional treatments, everything from
7 functional medicine to natural remedies, acupuncture,
8 sound bathing. I've pretty much tried everything that I
9 can think of or that I've seen on the Internet in order
10 to find some relief.

11 So I am very thankful for this opportunity to
12 be here before you and to share my experience with the
13 other people who are dealing with the daily impacts of
14 long COVID. And I definitely think that this is a very
15 important conversation and I am thankful for this
16 opportunity in this platform and everyone who is
17 participating in hopes that we can continue to move
18 forward, continue to find research and continue to find
19 a resolution for all of us who are suffering. Thank you
20 very much.

21 MS. BENT: Thank you. Thank you so much,
22 Heather-Elizabeth. I suspect that many of the
23 experiences that you mentioned are going to resonate
24 with a lot of our meeting participants as far as the
25 symptoms go, and we're going to touch more on some of

1 these topics during the follow-on discussion.

2 Now, Linda, we're going to ask you to turn on
3 your camera and share your experiences with long COVID.
4 So please go ahead.

5 MS. VARNO: Good morning. My name is Linda
6 Varno. I am a pediatric long COVID advocate whose
7 husband and child, my son, are both experiencing long
8 COVID. I'm also the co-founder of Team Varno, which is
9 a personal blog dedicated to the care of a child with
10 long COVID. Thank you for the invitation to participate
11 today.

12 For the past 751 days, my 14-year-old son,
13 Aidan, has been experiencing effects of pediatric long
14 COVID. Aidan's symptoms, which have been documented on
15 our Team Varno Facebook page, began four and a half
16 months post-COVID infection. Even with multiple PCR
17 tests, Aidan did not have a positive result. However,
18 blood work taken at the time showed that he did have
19 COVID antibodies. For the past two years, Aidan has
20 experienced severe, excruciating, amplified pain that is
21 centralized to his lower right back and will diffuse
22 throughout his entire body. The pain, which does not
23 respond to pain relief medications, becomes so severe
24 that Aidan will experience nonepileptic seizures.
25 Additionally, he frequently loses control and function

1 of his body, which impacts his mobility.

2 Aidan has difficulty thinking, decreased
3 executive function, fatigue, heart palpitations, blood
4 flow problems, intermittent loss of speech, trouble
5 sleeping and is starting to forget what it was like to
6 not be in excruciating, unrelenting pain all day, every
7 day. These symptoms affect Aidan's quality of life and
8 his fluctuating care needs. Aidan now has a silo effect
9 in his medical chart, which includes over 12 different
10 diagnoses and multiple medical specialties.

11 His symptoms also ebb and flow, especially
12 with weather changes, and no two days of symptoms over
13 the past two years have been identical. The extreme
14 pain, brain fog, fluctuating mobility, intermittent loss
15 of function, lack of public awareness and lack of
16 financial support are some of the significant impacts
17 pediatric long COVID has waged on Aidan and our family.

18 Parents like me are having to quit their jobs
19 to be full-time caregivers and do not have caregiver or
20 supplemental financial support. The insufficient
21 understanding and compassion from the medical community,
22 access to quality care and options available to patients
23 and their families is limited. Currently, Aidan is
24 receiving care for his amplified pain at a
25 neurorehabilitation clinic that is 15 hours away from

1 home and 100 percent out of pocket. This is the reality
2 of what families across the U.S. are doing to help their
3 children get better. Anything.

4 A specific activity that Aidan cannot do as
5 fully as he used to is his schooling. The mental
6 fatigue, academic requirements and attendance laws have
7 been huge hurdles for someone with medical documentation
8 of symptoms that ebb and flow. Even with accommodations
9 and parents who genuinely care about his education and
10 future, he is struggling. These kids are truly fighting
11 for their lives. It's not an exaggeration.

12 Mental health care and pediatric patient
13 support groups are needed for pediatric long COVID
14 patients, their siblings and families, more than you
15 know. Being part of a caring community matters.

16 Lastly, I want you to know that millions of
17 children experiencing pediatric long COVID, whose
18 disabilities, both visible and invisible, along with
19 their families, are suffering, experiencing unimaginable
20 trauma and are counting on your help. We are clinging
21 to hope. Thank you.

22 MS. BENT: Thank you, Linda. Thank you for
23 being here and for sharing Aidan's story. I know that
24 he had given you permission to share his story and we
25 really appreciate hearing what it has been.

1 MS. BENT: So now we're going to turn to
2 Estefania. Estefania, please go ahead and share your
3 experiences.

4 MS. OTERO: Thank you for the invitation to
5 talk about my life with long COVID. I'm 52 years old, I
6 live in Spain, and in January of 2021, I had COVID. I
7 didn't vaccinate. I'm a doctor. The impact in my daily
8 life is complete. I denied it in the beginning, and I
9 was depressed and I needed help. And during these two
10 years, I've learned to live with the disease. I've
11 learned to organize my days and to avoid physical and
12 mental fatigue as possible. This implies physical
13 training in the mornings to recover my muscle mass and
14 maintain it. I sleep for two hours or whatever is
15 necessary to study or to read in the afternoons. And
16 I'm lucky to have a husband and children who are
17 grownups, who help me and have supported me throughout
18 the process.

19 The symptoms have evolved over time and they
20 have improved regarding intensity. Physical fatigue, it
21 was overwhelming. I lost almost all the muscle mass.
22 But once I recovered it, it still doesn't work. I have
23 many limitations and I have to distribute it
24 consciously. And I have pain. I used to run half
25 marathons. Not anymore. I have a different pain. It's

1 a very intense pain that is not related to previous
2 activity. Brain fog has improved. I'm able to read
3 more. For many months I didn't remember anything I read
4 and this produced anxiety. And I only listened to music
5 or read simple things. I still train on this, assuming
6 that I forget many things I learn. For instance, if I'm
7 interested in a medical issue, I make slides about it,
8 although when I see them, I do not remember I made them.

9 Brain fog and physical fatigue prevent me from
10 doing my previous work as an ER physician because I
11 might not remember something quickly so as to treat my
12 patients despite I have all the information in my cell
13 phone. And also they are not able to go quickly to the
14 third floor without a lift and not even walk through a
15 hill or to do prolonged resuscitation. I'm in medical
16 leave and I'll see if I am able to go back to work as a
17 doctor.

18 This has also affected my personal life. I
19 can't have a spontaneous life anymore. Now I have to
20 plan and have a plan B just in case I have a bad day and
21 I sleep little. I can't be out with friends late. I do
22 not go to clubs anymore and, well, we go out at noon.
23 Well, you can't stop living. You have to enjoy. It's
24 very hard. But we are survivors of COVID and we have to
25 make the most out of it. And that's it. Thank you very

1 much everyone, and I encourage you.

2 MS. BENT: Thank you, Estefania. We're really
3 hearing a diversity of experiences with some very common
4 themes. And so for our next panelist, we're going to
5 hear from Katie who's going to share her experience.

6 Before we hear from Katie, let me just ask our
7 panelists to speak slowly so that the interpreters are
8 able to capture the full text of what you are saying.
9 So Katie, thank you so much and please go ahead.

10 MS. DRACKERT: Hello, everybody. My name is
11 Katie. I'm an artist, a first generation college
12 student, a friend to many and a daughter to my sweet
13 parents. Before long COVID, I was a dancer, practicing
14 for at least 45 minutes at a time and taking on gigs
15 that required hours of stamina. After a year and a half
16 of long COVID, I still don't feel confident reclaiming
17 my dancer title. Summarizing one of the most painful
18 chapters of my life into a few minutes is difficult, but
19 I will give it my all in hopes of furthering an
20 accessible recovery process.

21 Fatigue mixed with brain fog has been one of
22 the most debilitating symptoms. The silent and
23 invisible symptom has created a negative domino effect
24 in my life. They are as follows: struggling with basic
25 care such as cooking, not being able to keep or find

1 accommodating jobs, inability to read without quickly
2 tiring, falling behind in school, leading to dropped
3 classes. Dancing pushed me into fatigue spells that
4 lasted for days, shelving my art career. A negative
5 impact on my personal relationships. Muscle loss due to
6 being sedentary, causing my hypermobility issues to
7 worsen, leading to more injuries. A need for more
8 doctors' appointments, which creates more medical debt.
9 High stress due to financial instability, thus worsening
10 the fatigue. And the financial stress has been so
11 strong from my lack of ability to work that I actually
12 experienced food insecurity for the first time.

13 I often find that those who have not
14 experienced fatigue struggle to understand what it is
15 like. So I created some imagery. It's as if your inner
16 dialogue becomes full of static, making it difficult to
17 sort through your thoughts without further exhausting
18 yourself or fatigue is like a phone that has been
19 charged all night long only to drop to 10 percent after
20 one call, which I think a lot of us have maybe
21 experienced, and I just don't want this symptom to be
22 underestimated.

23 Next is depression. My friends would tell you
24 that prior to long COVID, I managed anxiety, not
25 depression. I was a person fueled by hope. I was

1 anxious, but I was definitely hopeful. The long COVID-
2 fueled depression dissolved my hope. It furthered the
3 negative impact on my personal relationships. I could
4 no longer feel joy, purpose or motivation. I would have
5 very excessive crying spells out of nowhere, sleep
6 issues and suicidal ideation. All of this made it
7 harder to find an accessible job, school more difficult
8 and further fueled the fatigue.

9 Before my second COVID infection, I thought I
10 was experiencing pure grief. I didn't experience the
11 full-blown effects of this deposition until around six
12 weeks after my second COVID infection in May of 2022.
13 It felt like a switch had flipped in my brain and I knew
14 what was logistical and I knew that hope existed, but it
15 didn't exist within or around me. The severity nearly
16 put me in an inpatient program and I could not pull
17 myself out of this depression alone. It required
18 intervention from friends, my therapists and doctors.

19 And finally, it worsened my preexisting
20 medical issues. Prior to long COVID, I knew it was
21 likely I had endometriosis, but at least it was somewhat
22 mitigated with over-the-counter treatments. And once
23 long COVID came into the picture, my period pain was so
24 debilitating that I went to the emergency room twice.
25 They gave me prescription pain medication and that did

1 little to nothing. My cycle became excruciating for 25
2 days out of the month, and once again, long COVID stood
3 in between me and bettering my future. It made my
4 asthma and my allergies much worse. Before my
5 infections, I only needed an inhaler when I experienced
6 a common cold, and now I need it on a regular basis.
7 And at times I require a nebulizer.

8 Asthma and allergy issues made it difficult to
9 complete daily tasks. The shortness of breath I
10 experienced on a consistent basis was absolutely
11 horrifying. Simple things would cause shortness of
12 breath, and as a dancer, this completely broke my heart.

13 I hope we can all work together to find
14 sustainable solutions for us and relieve the isolation
15 that long COVID has brought into our lives. I hope
16 listening to us today fosters empathy for the dire need
17 for treatments. Thank you so much for caring enough to
18 show up today. And thank you for taking the time to
19 listen as to how long COVID has changed my life.

20 MS. BENT: Thank you, Katie, for sharing your
21 experiences. And our final panelist for this topic
22 we're going to hear from is Sudeepti K. So let me ask
23 Sudeepti -- you already have your camera turned on.
24 Excellent. And please go ahead and share your
25 experiences.

1 SUDEEPTI K: Sure. Thank you for having me
2 and thank you for everyone that has put this long COVID
3 day together. I'm sure as you're hearing through the
4 experiences here today, some of us patients who have
5 been going through this really appreciate the strides
6 that FDA is making in this direction to make our voices
7 heard.

8 So prior to contracting COVID, I was a very
9 healthy 30-year-old. I was very active around the
10 house, had a very busy social schedule, had vacations
11 planned and weddings and a very active lifestyle. I
12 contracted COVID in June of 2022 and the day I tested
13 positive and went to go get a positive test at the local
14 urgent care, they noticed that my blood pressure and my
15 heart rate were a little high. But they said that that
16 was pretty common with folks that are dealing with an
17 acute infection of COVID. They did an EKG to make sure
18 my heart was okay and said that some of the chest
19 tightness should subside after the acute infection.

20 So as I went through the infection, I would
21 say I had a mild to moderate case of COVID at the time.
22 And after I tested negative, I started noticing that my
23 chest tightness wasn't fully going away and my heart
24 rate wasn't fully back to normal either. It just kind
25 of continued resting. And then I had what I now call as

1 a high heart rate episode where I could either be active
2 or completely resting, sitting on my couch, and my heart
3 rate will suddenly shoot up to like 190 or 200 and
4 typically deep breathing will bring it down. But the
5 first time that happened, I also had shortness of
6 breath, my oxygen had dropped and it was a very scary
7 episode to experience for someone that has never had any
8 other health issues prior to getting COVID.

9 So I was put on a beta blocker for these
10 symptoms. But as kind of the weeks went on into July
11 and August, I noticed that I was having persistent chest
12 tightness going up into the neck region that where my
13 sore throat during COVID was the worst is, to this day,
14 a sore spot for me. If I drink a warm beverage, I can
15 feel exactly where the sore throat was that bad. And I
16 was put on a beta blocker to help control my heart rate.
17 But a lot of times even going from reclining to sitting
18 up or sitting to standing would shoot my heart rate up.

19 I wasn't really able to do daily activities,
20 cleaning my pets' litter, cooking, even showering and
21 exposure to heat or high temperatures was extremely
22 exhausting and I would just have to sleep for hours.
23 Over time, the beta blocker has been helpful. I was on
24 it for about six months and recently got off it because
25 I was starting to see some recovery. So I stopped the

1 beta blocker in January, started to feel fairly normal,
2 and then my husband broke his wrist a few weeks ago, and
3 just the compounded stress of having to take care of him
4 and a relapse in my pets' health has caused a complete
5 relapse for me. So I feel like I'm back at stage one,
6 but potentially worse.

7 So there are some things that are better. The
8 chest tightness is now better, but now any kind of
9 emotional or physical stress, and by physical stress, I
10 mean cooking a meal can count as physical stress. So
11 walking downstairs to get my mail counts as physical
12 stress, will bring all the symptoms back. So I've had,
13 in the last couple of weeks, actually several emergency
14 room visits, a couple 9-1-1 paramedic calls, because my
15 heart rate will be so high that I feel like I'm going to
16 pass out.

17 My tests have all come back normal. I've had
18 several images and blood work and things. So it's
19 really an enigma as to what might be going on. But the
20 persistent heart issues are still very much a reality
21 after what I thought was improvement over the past few
22 months. So I'm really happy to be able to be here and
23 share my experiences, hear from others that might be
24 going through similar things. And again, thank you to
25 FDA and team and collaborators for putting this

1 together.

2 MS. BENT: Thank you so much, Sudeepti. We
3 really appreciate your sharing this. There's a lot to
4 unpack with everyone's experiences. And we need to
5 thank Jill and Heather-Elizabeth, Linda, Estefania,
6 Katie and Sudeepti for sharing. And they did this
7 really to help us move the field of long COVID forward.
8 So thank all of you.

9 So let me maybe turn briefly to my FDA
10 colleagues to see if they have any clarifying questions
11 for any of our panelists and to see if they have any
12 thoughts on what they've heard.

13 Yes, please. Rear Admiral Iademarco?

14 DR. IADEMARCO: Yes. Thank you. It was
15 really, really good to hear those presentations, and I'm
16 sure it was very difficult to put them in terse terms.
17 This was touched upon, but I wouldn't mind hearing from
18 one or two of the panelist speakers/patients to describe
19 a little more about the interaction with navigating the
20 healthcare system, and especially the interaction
21 between primary care and, if necessary, specialty care.

22 MS. BENT: Sure. So let me maybe turn to --
23 we'll go to Katie and then Heather-Elizabeth, and then
24 Linda, and I'll just ask if you could keep your comments
25 as brief as possible because we do want to also be able

1 to turn to people on the phone. But when I say brief, I
2 do not mean fast. So please go ahead and speak slowly
3 so that we can interpret it appropriately. Thank you.

4 MS. DRACKERT: Absolutely. Thank you. And
5 thank you for that question. So my situation with
6 navigating the healthcare system required a lot of
7 waiting. So I will say I'm lucky enough to have pretty
8 good health insurance and a long-term relationship with
9 a primary care provider. But even with that access, I
10 still had to wait three months to get into a long COVID
11 clinic, and I had to wait months to see certain
12 specialists. Just a lot, a lot of hurrying and then
13 waiting was my experience. And most of the time, I
14 would say about half the time I was believed, and then
15 half of the time I would be a little put down or
16 dismissed because I'm young, I'm 28, and yeah, that's a
17 little bit about my experience.

18 MS. BENT: All right. Thank you, Katie.
19 Heather-Elizabeth?

20 MS. BROWN: Hello. Thank you. I would say
21 that I have had a very interesting experience with the
22 healthcare system since my experience. I have been
23 fortunate that I do have a very comprehensive health
24 plan through my employer. So a lot of the medications
25 that I've had over the past three years, some of them

1 have been upwards of \$1,000 to \$2,000 per refill that my
2 insurance has covered for the most part. And
3 additionally, a lot of the specialists and providers
4 that I have found have been through my initial
5 hospitalization and treatment for COVID, which I think
6 has eliminated a lot of the issues that many people have
7 had with being gaslighted, with gaslighting, with
8 medical professionals, with issues with not being
9 believed or having their symptoms overlooked because a
10 lot of the providers that I worked with were the same
11 ones who saw me in the hospital when I was first there,
12 who got me through the initial hospitalization or were
13 able to bring me through the coma or some of the other
14 things that I've dealt with.

15 But I will definitely say that it has still
16 been challenging. I similarly had to wait a long time
17 to be admitted to the long COVID clinic here in
18 Michigan. My waive was eight or nine months, and so it
19 was quite a long time before I was able to be seen and
20 then actually scheduling those appointments. So it has
21 been an exercise in patience and faith. However, I do
22 find that learning and having information about being
23 your own advocate as a patient has been invaluable. And
24 that's something that I have gotten more information
25 from with a lot of the long COVID support groups and

1 other organizations that I've been able to participate
2 with. And I think that that's something that needs to
3 continue to be addressed and presented to long COVID
4 sufferers who need to advocate for themselves when it
5 comes to getting proper health or medical care and
6 connecting with providers who are going to help them
7 move in the right direction in terms of recovery. Thank
8 you.

9 MS. BENT: Thank you. And Linda?

10 MS. VARNO: Yes. Thank you. Great question.
11 I want to highlight that when my son started having
12 symptoms of pediatric long COVID, long COVID wasn't even
13 terminology used. So initially, when we were seeking
14 care out for Aidan and his anomaly of symptoms that were
15 occurring, my husband and I were actually abused -- or
16 excuse me, were actually accused of abusing our child or
17 sexually abusing our child. And so that's how we were
18 presented with happenings initially. So we were moving
19 from healthcare system to healthcare system because no
20 one was believing us, no one would listen to our son and
21 they were looking at it from a psychiatric breakdown.

22 So initially our options in April to May of
23 '21 were to put our beautiful, healthy prior to all of
24 this 12-year-old son into a skilled nursing facility, to
25 place him in a pediatric psychiatric unit or to look at

1 pain programs which weren't comprehensive enough to
2 really meet all the needs Aidan was seeking.

3 So for nine months we went without any
4 provider helping us to really hone in on all of Aidan's
5 problems and get us to where we needed to be because
6 even our own wonderful, amazing pediatrician who has
7 been with Aidan since day one just kept saying we need
8 to get to specialists. Who are they? Where are they?
9 So, for us, highlighting what Heather said, familial
10 advocacy and also starting crowdsourcing through our
11 Facebook page is really what led us to getting quality,
12 amazing care at Rainbow Babies and Children's Hospital.
13 So, thank you.

14 LARGE-GROUP FACILITATED DISCUSSION ON TOPIC 1

15 MS. BENT: Thank you, Linda. Really, really
16 appreciate you. And so sorry to hear about Aidan's
17 experience. So now we are going to take a few calls.
18 We're going to start with Christine on line one. So let
19 me see if we can do that. Christine, can you hear us?

20 CHRISTINE: Yes. Yes, I can. Can you hear
21 me? Hello?

22 MS. BENT: I'm not sure that we have any sound
23 from the phone. So we'll just give it a minute to see
24 if we have any sound from the phone.

25 CHRISTINE: Can you hear me now? Can you hear

1 me now? Can you hear me now?

2 MS. BENT: Yes. Yes, we can. Thank you.

3 CHRISTINE: Oh, great. Can you still hear me?

4 Okay.

5 MS. BENT: Yes.

6 CHRISTINE: Great. Hi, everyone. Before my
7 COVID infections in 2020, which were mild, acute
8 infections, I had a very full life. I was 35 years old,
9 working the job of my dreams in international
10 development. I traveled the world frequently. I had a
11 robust social life and was a devoted daughter. I loved
12 dancing and skiing.

13 Since my COVID infections, I am no longer able
14 to work any job, even part-time. I am primarily
15 housebound and frequently unable to do activities of
16 daily living, like changing my clothes. The ability to
17 shower is rare for me. I am unable to communicate with
18 family and friends without significant physical and
19 cognitive repercussions. When I try to do too much,
20 such as stay on a phone call too long or do house
21 chores, I become mostly bedbound for a day to a week.
22 I've gone for months feeling disoriented, as if my brain
23 is inaccessible to me only because I used my brain too
24 much over the course of one or two days.

25 I struggle with over 30 long COVID symptoms.

1 My diagnosed post-COVID conditions are ME/CFS,
2 neurocognitive disorder, POTS, MCAS, small fiber
3 neuropathy and CIDP. The symptoms that have had the
4 most significant effect on my life are cognitive
5 impairment and debilitating fatigue; more specifically,
6 the worsening of these symptoms following any kind of
7 physical or cognitive exertion.

8 In almost three years, I have not stopped
9 seeking treatments that might help. I am fortunate to
10 see several specialists regularly, including, but not
11 limited to an ME/CFS specialist, neurologist, allergists
12 and immunologists, psychiatrists, gastroenterologists
13 and physical therapists for my neck pain. I often see
14 additional specialists for second opinions. I follow
15 several sources that report on potential long COVID
16 treatments. I stay in touch with a large international
17 group of friends with long COVID with whom I discuss
18 which treatments we are trying and what is and isn't
19 working.

20 A successful treatment would enable me to
21 exert physically and mentally without worsening my
22 ability level and sickness symptoms. It is imperative
23 that decision-makers at the FDA understand that drugs
24 that simply boost fatigue or cognitive function --
25 sorry, boost energy or cognitive function on any given

1 day are not a solution and can even be harmful.
2 Whenever I try a drug that improves my energy levels or
3 my cognitive function, I exert more than I would
4 otherwise physically or cognitively. And within a week,
5 I end up in a much worse state that cannot be helped by
6 medication, typically bedbound without enough energy to
7 grab things from my nightstand and disoriented and
8 unable to stay on a specific thought for five seconds.

9 Instead, we need treatments that prevent post-
10 exertional symptom exacerbation. It is critical that
11 the FDA takes this into account when reviewing clinical
12 trial design. Thank you for your time.

13 MS. BENT: Thank you, Christine. Really
14 appreciate you taking the time to share your thoughts
15 with us. Let me now turn to Shawnee on line two.

16 SHAWNEE: Hello?

17 MS. BENT: Hello. So I can't hear Shawnee or
18 the interpreters, but once I can, I will just ask people
19 to remember to speak slowly so that the interpreters are
20 able to interpret. So Shawnee, if you can, go ahead.
21 Okay. So we're going to go ahead and try to get Shawnee
22 back. Let me turn maybe now to Shannon to see if we
23 have any comments that we want to share at this point in
24 time.

25 Shannon, are we ready to share some of those

1 comments or should we move on to polling?

2 MS. SPARKLIN: Yes. I have some comments that
3 I can share.

4 MS. BENT: Great.

5 MS. SPARKLIN: A lot of the comments that
6 we've been receiving have been stating that they
7 resonate with what the patient panelists shared earlier
8 during the panel. Regarding some of the major symptoms,
9 I am seeing comments related to blood pressure issues,
10 tingling and pain, light-heartedness, dizziness, brain
11 fog and onset dizziness, eye redness, pain and blurry
12 vision. One panelist -- or one written comment said
13 that it feels like they're walking on a boat when
14 they're walking and that they experience severe
15 headaches, chronic insomnia, sore throats, rashes and
16 that they experience difficulty standing and only laying
17 down had helped their symptoms with that.

18 So overall, a lot of the comments are
19 reflective of what we have heard so far. But I will
20 continue to monitor the comments to see what else we
21 receive.

22 MS. BENT: Thanks, Shannon. So let's now move
23 on to just to some polling questions. As we mentioned
24 previously, polling is still limited to participants who
25 have lived experiences with long COVID, either as

1 somebody with long COVID or as family members or loved
2 ones. And so we will now move on to that. And so the
3 first question that we have is how long or after your
4 COVID-19 illness did you begin having symptoms of long
5 COVID? And so please select the motion: A, 0 to 1
6 month; B, 1 to 2 months; C, 2 to 3 months; D, 3 to 6
7 months; E, 6 to 12 months; F, 12 to 24 months; or G, 24
8 to 26 months or other.

9 Okay. It looks like we're seeing a majority
10 of people who felt like their symptoms really started to
11 appear within that first month after their COVID-19.
12 But it does look like we're seeing kind of
13 representation from across the across the options with
14 one to two months and two to three months being kind of
15 the more common. So thank you. That's helpful
16 information.

17 Let's move on to our next polling question.
18 Which of these symptoms have you experienced because of
19 your long COVID? Please select all that apply: A,
20 pain, including headaches; B, learning, attention or
21 memory difficulty, for example, brain fog; C, weakness
22 or fatigue; D, shortness of breath or cough; E, racing
23 heartbeat, dizziness, postural tachycardia syndrome,
24 also known as POTS; F, post-exertional malaise or
25 exercise intolerance; G, depression and/or anxiety; H,

1 difficulty falling asleep or staying asleep, such as
2 insomnia; and I, other.

3 All right. So it looks like we're seeing a
4 range of symptoms and kind of a combination of symptoms
5 across the board and so with really the attention and
6 the weakness and fatigue being currently top but
7 obviously significant impact from the racing heartbeat,
8 the post exertional malaise, the insomnia and others as
9 well.

10 Okay. So now we're going to move on to the
11 next question. Now this next question has the same
12 options as the last question, but in this question we're
13 asking you to select the top three answers about which
14 symptoms of your long COVID are most bothersome to you.
15 And so you can select three. And again, those answers
16 are, A, pain; B, learning, attention or memory
17 difficulty; C, weakness or fatigue; D, shortness of
18 breath or cough; E, racing heartbeat, dizziness,
19 postural tachycardia syndrome; F, post-exertional
20 malaise or exercise intolerance; G, depression and/or
21 anxiety; H, difficulty falling asleep or staying asleep;
22 or I, other.

23 And I will have to admit it's a little
24 difficult for me to see the answers. But I think we're
25 seeing that the weakness or fatigue, the post-exertional

1 malaise and the attention -- difficulty with attention
2 such as brain fog are really coming in as the things
3 that people find the most bothersome with pain also
4 being a significant factor and the racing heart rate or
5 POTS. So we're really seeing that all of these are
6 having a significant impact on the people who are
7 answering the questions for this polling. So thank you
8 for providing us with that information.

9 And then let's turn to our final polling
10 question before we turn back to our callers on the
11 phone. And so this is the final question. What do you
12 find to be the most disruptive aspects of long COVID on
13 your daily life? And again, please choose up to three
14 answers: A, lost productivity, such as not being able to
15 work as much as you want or being able to attend school
16 to the extent that you need to; B, loss of physical
17 function; C, loss of job; D, impacts on relationships
18 with family and friends; E, emotional or psychological
19 impacts; F, cognitive effects such as thinking and
20 remembering; G, other; and H, none of the above. And
21 I'm sure that this question is kind of difficult because
22 it's really hard to pick the top three for things like
23 this, right? But we appreciate just the fact that
24 you're willing to kind of think about this and share
25 your thoughts with us about this.

1 So we're seeing it looks like the cognitive
2 effects are a significant impact. Lost productivity is
3 significant. The loss of physical function is
4 significant. Obviously, the impact on relationships
5 with family and friends is also really significant to
6 people. And so thank you for sharing this.

7 And we're now going to turn kind of back to
8 the phones. And so let us turn to Robert on line six to
9 share some of his experiences with long COVID.

10 Robert?

11 ROBERT: Can you hear me?

12 MS. BENT: Yes.

13 ROBERT: I'm a long COVID caretaker, and what
14 we'd like you to know, my fiancée and I, is that my
15 fiancée says she feels like she's disappearing. A year
16 ago, we could walk one mile together, and a few weeks
17 ago, we couldn't make it to the mailbox. She sits
18 upright for less than 30 minutes per day and stands for
19 less than 10 minutes, never consecutively. Sometimes
20 she doesn't have enough energy to speak. Doing a
21 crossword puzzle together this past Sunday began to
22 deplete her. We can't go to a friend's birthday party,
23 a wedding or even walk the dog to the park one block
24 from our home.

25 We are missing from public life, and what's

1 happening to her is happening to me. Because of her
2 sleep issues, I now sleep on the sofa every night, and
3 I'm just hoping that it'll help her sleep better and
4 heal more if I'm in a different room. And then in the
5 morning, I wake up and I make breakfast and lunch for
6 her, and I put it on the table outside the bedroom as
7 quietly as I can so that she can get up and walk a few
8 feet as she needs to eat and hydrate herself. And then
9 I go to work, and then I come home and I do the same
10 thing for dinner and we have a few precious hours every
11 day where we can run the risk of talking and enjoying
12 each other's company without depleting her. So long
13 COVID has transformed our lives completely and we
14 desperately need help.

15 MS. BENT: Thank you, Robert. I'm so sorry
16 that you're going through this and thank you for taking
17 the time to call in and share your experiences with us.

18 Let me now turn to Shawnee on line two.

19 Shawnee? Hi, Shawnee. Can you hear us?

20 SHAWNEE: Can you hear me now?

21 MS. BENT: Yes. Please go ahead. I don't
22 hear any speaking.

23 SHAWNEE: Hello? Okay. My name is
24 (indiscernible). I experienced long COVID, but I am
25 also epidemiologist working with the symptoms and this

1 condition. In my personal experience, I moved from
2 Puerto Rico to work with COVID-19 in East Texas in
3 October 2020. I got sick with COVID-19 in January 2021
4 and I had to leave my job and come back to Puerto Rico
5 because I was not able to do my daily living activities
6 by myself. I fell related with chronic fatigue
7 syndrome. I could barely stand to take a shower or walk
8 short distance. I developed dysautonomia, like an
9 orthostatic pressure problem. I experienced dizziness,
10 palpitations or irregular heart rate, and I also
11 experience detrimental lung function. I expand more
12 than six months receiving respiratory therapy like three
13 times per day. I had to buy a portable respiratory
14 therapy machine.

15 I've suffered from asthma since I was child.
16 But after COVID, I had new triggers for my asthma and I
17 could have an asthma attack any moment. I also
18 developed depression, anxiety and post-traumatic
19 disorder. I had visited family medicine, to
20 pulmonologist, to cardiologist and endocrinologist.
21 Because my blood sugar was high. I started to receive
22 medicine to control my blood sugar level. However, the
23 doctors claimed that I was young and the other results
24 of the test were normal. So I was supposed to be fine,
25 even I didn't feel well. So basically the only doctor

1 who treat me instantly was a pulmonologist
2 (indiscernible). They gave me treatment to stabilize my
3 asthma, although they say by the time that they didn't
4 know the cause of those post-COVID symptoms.

5 So I basically had to conduct my own research
6 to know what kind of recovery measures I can apply to
7 myself. So I didn't receive physical therapy or
8 referral to a rehabilitation program. I do had to visit
9 a psychologist for the anxiety and depression because it
10 was hard to know that I was not the same person I was
11 before COVID. So I spent two months unemployed because
12 I was not able to work. I had to regret accepting a job
13 offer with benefits as an infection control coordinator
14 in Florida. And then after two months of that, I
15 started to work in Puerto Rico as well as an infection
16 control coordinator. But I didn't feel well enough yet
17 to drive or to walk. I had to do it because I was
18 economically compromised.

19 So when I started to work, I noticed that I
20 couldn't do the rounds in the hospital with the same
21 ability that I used to. I had to take breaks in the
22 middle of my shift and get some rest in my car and then
23 go back to work. I also experienced brain fog, but
24 fortunately I got a position as a disease intervention
25 specialist developing a surveillance system for long

1 COVID in Puerto Rico which required less physical
2 effort, but my brain fog made my performance difficult.

3 MS. BENT: Thank you.

4 SHAWNEE: I had a problem interacting with
5 colleagues and it's something that I am still working
6 with it.

7 MS. BENT: Thanks, Shawnee. That really is
8 great of you to call in, and I apologize for the audio
9 issues that we had kind of to begin with. But thank you
10 for hearing your experience. It seems like it's had a
11 huge impact on your life. So thank you.

12 So now let me turn to John on line seven.
13 John, I'm wondering if, once we get you on the line, if
14 you could maybe think about answering a question or two
15 for me, if you'd be willing.

16 JOHN: Sure. What's the question?

17 MS. BENT: Thanks. Yes. So are there any
18 specific activities that are important to you that you
19 can't do or do as fully as you'd like because of your
20 long COVID?

21 JOHN: Absolutely, and I think the activities
22 are the ones that would help my family. I used to cook
23 all the dinners, I used to clean up downstairs, I used
24 to take the kids to the park and I can't do any of that
25 physical stuff anymore. And I really have a lot of sort

1 of internalized shame around not being able to provide
2 for my family by working and doing those tasks anymore.

3 MS. BENT: Thank you. Is there anything else
4 that you wanted to -- I know I kind of took you off of
5 what you called to talk about. So is there anything
6 else that you wanted to talk about related to your long
7 COVID that you'd like to share briefly with us?

8 JOHN: Sure. I can do it real briefly. Yeah.
9 I'm young. I was vaccinated. I had a really mild
10 illness or acute illness and I just never got better.
11 I've got a family with two young kids, used to be very
12 athletic and used to run and ski, work full-time. And
13 after COVID, I just -- something wasn't right. I was
14 weaker. My heart rate started spiking. Contacted the
15 doctor, they had no idea how to treat this. They said,
16 just don't worry about it, and then just declined from
17 there and realized I have really bad post-exertional
18 malaise.

19 And that's just the important thing. I want
20 to echo some of the other speakers is that the post-
21 exertional malaise is the most limiting symptom. I
22 could deal with the fatigue. I could deal with
23 everything else. I could push through it and get what I
24 needed to get done. But because I have that payback
25 with the post-exertional malaise, I have to really limit

1 my activities. So if there's some sort of treatment
2 around lowering that or letting our bodies recover, I
3 think that's the most important thing for the FDA to
4 hear.

5 MS. BENT: Thank you. Thank you. Really
6 appreciate that. Let me turn to Anne Marie on line ten.

7 ANNE MARIE: Hello?

8 MS. BENT: Hi, Anne Marie. I'd like to hear
9 about your experiences, and it sounds like the
10 experiences of maybe your child with long COVID. Also,
11 I think if you wouldn't mind talking to us a little bit
12 about whether your long COVID has changed over time from
13 its original diagnosis to now, that would be great for
14 us to hear about. And once again, just a broad request
15 to speak slowly so that the interpretation is accurate.

16 ANNE MARIE: Sure.

17 MS. BENT: Thank you so much.

18 ANNE MARIE: Like many of you, I'm no longer
19 afraid of the acute COVID illness. But I've learned the
20 hard way that the story doesn't end when the initial
21 symptoms subside. At the end of March 2022, three of
22 the six of us in our house contracted COVID for the
23 first time. We were all fully vaccinated and boosted.
24 Despite being young and healthy, my 14-year-old son Luke
25 and I never fully recovered after our infection. Luke

1 initially improved slightly, but after overdoing it at a
2 Scout event in May, he went into a huge crash that he
3 has still not recovered from. He is now only doing
4 school virtually from either bed or the couch.

5 While I had been substitute teaching, I now
6 struggle to take care of my basic needs or do an
7 occasional chore. We are shells of the people we were
8 before COVID and lead a very limited life now. For the
9 first few months, I just waited and expected we'd get
10 better. But eventually I realized I needed to start
11 researching, and I haven't stopped learning ever since.
12 We've seen dozens of doctors, both locally in New York
13 City and Philadelphia. We've had blood work, x-rays,
14 MRIs, CAT scans, ultrasounds, physical therapy,
15 myofascial release therapy, chiropractic and acupuncture
16 with the hopes that someone is going to be able to help.

17 But the truth is there is no cure and no one
18 is an expert because long COVID is still too new. There
19 are only things to help minimize the symptoms to help us
20 function a little better. In addition to the cost for
21 all of this, which isn't all covered by insurance, the
22 energy to figure out what to try, where to go and then
23 actually attend all these appointments is truly
24 exhausting. I've been diagnosed with dyssomnia, cough
25 and mild emphysema despite never having smoked. And I'm

1 exploring hypermobility, connective tissue diseases,
2 ME/CFS, craniocervical instabilities. So the work is
3 not done.

4 We both spend about 90 percent of our day
5 laying down. We are not able to have our legs down or
6 our heads up for any period of time. Our biggest issue
7 is debilitating fatigue, fatigue that makes me struggle
8 to hold my arm up long enough to brush my teeth or wash
9 my hair. It's debating if I should just deal with the
10 pain from laying in one position for too long because
11 the idea of getting enough energy to roll over is
12 unbearable. It's watching my once active teenager crawl
13 up the stairs to get to bed.

14 The second most challenging symptom is post-
15 exertional malaise, or PEM. Even if we think we have
16 the energy to do simple tasks, we run the risk of having
17 PEM afterwards. It can take several days after any kind
18 of physical, mental or emotional energy for it to catch
19 up with us, making our 20-plus symptoms flare.

20 Because of these symptoms, our family has
21 missed out a lot over the last year. We had to cancel
22 our family vacation to Disney last summer. We have no
23 idea if or when we'll be able to reschedule, as we don't
24 even have the ability to be upright long enough to have
25 dinner at a restaurant, let alone take a big trip like

1 that.

2 MS. BENT: So thank you for sharing that.

3 ANNE MARIE: I'm sorry. I have more to add,
4 if possible.

5 MS. BENT: Sure. We do have just about 10
6 minutes left before we go to break, and we do have a few
7 other callers on the phone. But if you want to finish
8 up, that would be -- that would be -- go ahead.

9 ANNE MARIE: Sure. (indiscernible) real
10 quick. There's a fine line between maintaining hope
11 that we'll be cured and learning how to live with a
12 chronic illness. Our physical therapist has been
13 critical in teaching us ways to improve our quality of
14 life. I cried leaving our first appointment because it
15 was the first time I felt like someone understood what
16 was going on. We've been taught that if we overdo it,
17 we could risk creating a long-term setback like what
18 happened with Luke.

19 The biggest thing we've learned is the need to
20 rest (indiscernible). I basically have 10 to 15 minutes
21 of being upright before I start to have problems. I
22 have a handicap placard for my car so I can limit my
23 walking, a shower chair, compression socks if we know
24 we're going to have our legs down for more than a few
25 minutes. I use noise-canceling earplugs and Luke wears

1 sunglasses for overwhelmingly heightened sensitivity.

2 I've learned how to feel better doing nothing. I'm not
3 yet able to feel better when I do much of anything.

4 While most of the world has moved on, COVID isn't over
5 for my family. Even the healthy members of our family
6 still take precautions out in public in order to avoid
7 getting infected, and either, A, getting long COVID
8 themselves since there seems to be anecdotal evidence of
9 a genetic connection, or, B, getting me and Luke sick
10 again and risk losing whatever progress we've made.

11 MS. BENT: Thank you. Let's turn now to
12 Sawyer on line three. Hi, Sawyer. Thank you for
13 calling in to share your experiences with us. Okay.
14 Moving on -- hello? Okay, We'll move on to Tina on
15 line four.

16 TINA: Hi. Thank you.

17 MS. BENT: Hi, Tina. I know that you might
18 have some things that you want to talk to us about, and
19 we'd very much like to hear them, but I'd also really
20 appreciate it if maybe you could touch on whether your
21 long COVID has changed at all from its original
22 diagnosis.

23 TINA: Sure, no problem. So I got sick in
24 July of 2020, and I will say that the first year and a
25 half, about 18 months, was the hardest. I was severe at

1 that point, possibly very severe. Now I'm moderate, so
2 it has improved a bit, not from any specific treatment
3 so much as managing my post-exertional malaise with
4 strict pacing. Also, I call it giving up everything you
5 love. So not walking, not trying to hike. I had to
6 stop working completely. I couldn't even manage working
7 from home.

8 Previously, right before COVID, I had
9 backpacked the Appalachian Trail, part of it, and I
10 volunteered for six different organizations. I worked
11 full-time as a project manager. I played ukulele and
12 sang. All of those things had to be given up. I'm now
13 diagnosed with long COVID, POTS and ME/CFS.

14 I just wanted to add that it really has stolen
15 almost the entirety of my life. I had to give up my
16 house and move in with my parents as well. I now use a
17 wheelchair to leave my house, to go shopping, and I have
18 a shower chair and other aides at home. I just don't
19 have an ability to be upright, to cook, to shower
20 upright, to walk, to socialize with friends or work in
21 any capacity without creating post exertional malaise.
22 To echo someone else, I can take stimulants to get
23 through the fatigue on a certain day. But I experience
24 a crash for anywhere from four hours to a month. Last
25 summer, I was bedbound for a month. So I just wanted to

1 add that this really has stolen my life away. So I
2 appreciate you holding this meeting and listening.
3 Thank you.

4 MS. BENT: Sorry about that. So let's turn to
5 the final call that we're going to be able to take
6 before moving to the break. I'm going to turn to Kailin
7 on line five to hear about some of your experiences.
8 So, Kailin, if you wouldn't mind just briefly giving us
9 a little bit about your experiences.

10 KAILIN: Yeah. Can you hear me?

11 MS. BENT: Yes, we can. Thank you.

12 KAILIN: Okay, great. Thank you so much for
13 letting me speak. I think my experience probably echoes
14 a lot of people's here. I was 30 years old, extremely
15 active, no preexisting conditions, and I went from doing
16 40-mile backpacking trips to about a month after getting
17 a COVID infection in June 2022 to basically being in bed
18 18 to 20 hours a day.

19 Like so many people who have spoken here, I
20 was diagnosed with POTS, postural orthostatic
21 tachycardia syndrome, myalgic encephalomyelitis or
22 chronic fatigue syndrome, and small fiber neuropathy.
23 And I'd like to emphasize that these are all lifelong
24 chronic illnesses with no known cure and there's very
25 little treatment. So I think in looking at treatments

1 with about half or more of people with long COVID
2 experiencing these other post-viral illnesses, it's
3 really important to look at the treatments and research
4 that's already out there with some of these post-viral
5 illnesses.

6 These illnesses lead to a whole large
7 constellation of symptoms, like a lot of people have
8 spoken. I have probably over about 30 symptoms once I
9 list them all out. And I would say in terms of
10 progression, in the first four to five months of my
11 illness, these were extremely limiting. I was working
12 full-time as a journalist and a videographer, and I was
13 completely unable to work for about nine months. I,
14 like I said, was in bed about 18 to 20 hours a day, and
15 lying down was the only thing that made me feel any sort
16 of any better.

17 I have everything from tachycardia, numbness
18 and tingling, to extreme heat and cold intolerance,
19 extreme fatigue, exercise intolerance, and a big thing
20 people have been talking about a lot, post-exertional
21 malaise, which I'd like to emphasize is a little
22 different from exercise intolerance. Sometimes I can do
23 an activity in the moment or exercise in the moment, but
24 then hours or a day or two days later, I'm left with a
25 severe flare-up of my symptoms.

1 The cognitive piece is also absolutely huge
2 one. I often find myself messing up words, unable to
3 find words, unable to write or swapping in different
4 words when I write, which is hard as a journalist and
5 often feel like I'm thinking through mud. And those
6 kind of post-exertional malaise crashes can be pretty
7 severe.

8 I've had people describe it to me, and this
9 sums up my experience pretty well as like a conscious
10 coma, like the world is going by around you. You can
11 hear everything, you can see what's going on, but you
12 can't move or speak or even really form thoughts. And
13 it's extremely disabling.

14 I have gotten a bit better, and the only way
15 that I have gotten better is with medications to deal
16 with POTS as well as just honestly extreme rest. Like I
17 said, being unable to work and just trying not to exert
18 myself as much as possible and practicing pacing,
19 periods of rest and exertion have helped. So I've
20 gotten a bit better, but I would not say I'm recovered.
21 I'm still nowhere near the person that I used to be.

22 MS. BENT: Thank you. That is helpful and I
23 appreciate you kind of speaking to the little bit of
24 improvement. I'm glad there's some. I certainly wish
25 that there was more for you and for everyone that we're

1 hearing from today. So right before we head to break,
2 and I know we're at time, but I'm going to turn to
3 Shannon just to give us a brief summary of the comments
4 that we received through the Web.

5 So go ahead, Shannon.

6 MS. SPARKLIN: Thank you, Robyn. We're seeing
7 several comments regarding flare-ups of symptoms and
8 symptoms that are random and unpredictable. I've also
9 seen several comments regarding exercise intolerance or
10 energy crashes related to post-exertional malaise.

11 Many people in the comments described how they
12 used to be very active and now they're unable to
13 exercise. They have energy crashes throughout the day,
14 and they're exhausted from simple activities.

15 I'm going to read a few comments that we
16 received regarding the impact of the symptoms of long
17 COVID on daily life. One individual stated that they're
18 not able to prepare their own meals, they eat cereal and
19 milk twice a day, they cannot clean, they're single and
20 live alone without family help and no financial
21 resources to pay for the things that they need.

22 Another commenter wrote in that they have had
23 long COVID for over nine months. Prior to getting acute
24 COVID and long COVID, they would bike 25 miles twice a
25 week and they were enjoying their best life. Now they

1 state that they cannot walk slowly for more than 30
2 minutes without getting post-exertional malaise the
3 lasts two to five days, which results in total fatigue.

4 Another commenter discussed their reduced work
5 availability and schedule and difficulties with being
6 self-employed and how their income has been reduced
7 dramatically as a result of their long COVID symptoms.

8 Another comment stated that I was a very
9 active mom who practiced yoga and ran half marathons
10 before I tested positive for COVID in April 2020. Three
11 years later, I still struggle with fatigue, severe brain
12 fog, migraines and the effects of POTS, which includes
13 heart palpitations, increased heart rate and painful
14 blood pooling upon standing. I have extreme issues with
15 ADLs such as showering and cooking. ADL stands for
16 activities of daily living. She stated that they're a
17 military family with their primary care doctor on base
18 and that continuity of care has been an issue as
19 physicians change bases often.

20 So those are just a few of the comments that
21 we have received. Thank you.

22 MS. BENT: Thanks, Shannon. So now we're
23 going to go to break. I apologize to those of you who
24 were on the phone who we weren't able to get to. Once
25 again, I do want to give a quick plug for the docket

1 comments. I think we've barely scratched the surface
2 today as far as the daily impacts of what you are all
3 experiencing on a daily basis. So please consider
4 sharing your comments to the public docket to expand
5 upon what you've shared so far. We're now going to
6 break for about 27 minutes and we'll be back to
7 reconvene at 12:45 Eastern Time. So thank you all and
8 thank you to our panelists and our callers who really
9 got this meeting off to a great start, and I look
10 forward to seeing you all back in just a few minutes.
11 Thank you.

12 (Recess)

13 TOPIC 2: CURRENT APPROACHES TO TREATMENT

14 MS. BENT: Welcome back, everyone. I hope you
15 had a great break. We have a limited time, so we're
16 going to move straight into topic two. As we mentioned
17 before, topic two will focus on current approaches to
18 treatment for long COVID, your experiences and your
19 perspectives on that, what you're currently doing to
20 treat your long COVID, and whether you feel like your
21 long COVID is well managed and finally, what are you
22 looking for in a treatment for long COVID.

23 We have five panelists who will start off our
24 discussion by sharing their experiences. And before we
25 launch into our panelists' experiences, I just want to

1 let you know that our first question for the open
2 discussion session is what are you currently doing to
3 treat or manage your long COVID, how has your treatment
4 regimen changed over time and why and what symptoms
5 would you like most to be improved or resolved by
6 treatment.

7 So now, as I mentioned, we're about 30 minutes
8 away from people calling in to share their answers. And
9 now I'd like to welcome our session two panelists and
10 thank them for joining us today. I'd like to start by
11 inviting Stephanie to share her experiences with long
12 COVID.

13 Stephanie, if you want to, go ahead.

14 MS. HUGHES: Sure. Thank you.

15 MS. BENT: Thanks.

16 MS. HUGHES: Thank you, Robyn. My name is
17 Stephanie Mitchell Hughes. I am from Columbus, Ohio,
18 and I've had long COVID since February of 2021. My
19 treatment for long COVID consists of being a patient at
20 the post-COVID recovery program that was established by
21 the Ohio State University Wexner Medical Center in
22 response to COVID-19 patients who were returning with
23 symptoms that some of which were not -- were very
24 different from what they experienced with the COVID-19.

25 And as a patient in the clinic, I received a

1 checkup initially across all of the major systems within
2 my body, including my lungs and my cardiac system, and
3 my long COVID affected from a physical perspective my
4 pulmonary system. And so I was sent to and became part
5 of the pulmonary rehabilitation department. And I also
6 at the same time became part of the physical medicine
7 department because I received treatment in the physical
8 medicine department for brain fog.

9 And with respect to the pulmonary rehab
10 department, in July of 2021, I started pulmonary rehab.
11 I completed 24 sessions of pulmonary rehab by October of
12 2021. The pulmonary rehab consisted of two sessions
13 twice a week on Tuesdays and Thursdays. And initially
14 we did an initial walking exercise just so that they
15 could gauge where we were.

16 I had a smaller group of people who -- two to
17 three other people who were in my group who were also
18 patients in the post-COVID recovery program. And we
19 also were constantly monitored by two to three
20 rehabilitation -- I'm sorry, respiratory therapists.
21 Our first exercise was the treadmill. As I am still
22 told, it is the most important machine that we used.
23 And we also used a bike. There was a bike that we used
24 and they have bikes of different levels that you can use
25 when you were doing the bike exercise. We also did and

1 worked on something called an arm ergometer. And then
2 we did some free weights and some standing and sitting
3 exercises.

4 The goal was not so much to increase
5 necessarily speed, but rather capacity and the length of
6 time that we were able to do a particular exercise or
7 work on a particular machine, and we were always
8 encouraged to work at our own pace.

9 One of the other things that they did was we
10 were also weighed. At the beginning of each week, we
11 were weighed to see if we were losing weight. And there
12 were also a few classes that we could call in and listen
13 to if we wanted.

14 I decided after the 24 sessions of pulmonary
15 rehab, and there are 24 sessions because that's the
16 number that my then health insurance paid for. And I
17 decided to continue on with pulmonary maintenance. And
18 I typically go to pulmonary maintenance on Tuesdays and
19 Thursdays in the early afternoon. And in pulmonary
20 maintenance, I work alone. I don't have -- well, the
21 respiratory therapists and other people in pulmonary
22 rehabilitation are there if we need to ask questions, if
23 I have questions or something like that. But I do
24 pulmonary maintenance alone. Unlike with pulmonary
25 rehab, I don't have a respiratory therapist asking me

1 how hard I'm working or measuring my respiration or
2 something like that. And so that's the one thing that I
3 continue to do consistently.

4 I also initially when I was working with
5 someone from physical medicine on brain fog, there were
6 a number of -- what they were trying were a number of
7 different medications that would treat symptoms. So,
8 for example, one of the medications that I took was an
9 old Parkinson's drug called, and I figured out the name,
10 amantadine and really didn't like that very much. And
11 so I decided to stop taking it. And I just continue if
12 I need to call in for support. There are a number of
13 different healthcare practitioners who I have in the
14 program, and I can call any of them for support at any
15 time. So my primary person is the person who I call my
16 long COVID internist.

17 MS. BENT: Thank you. That's great input.
18 It's wonderful to hear that you've been able to kind of
19 get plugged into care, and hopefully it's really having
20 a great impact. So thank you for that.

21 So I am going to move on to Jackie right now.
22 But thank you so much, Stephanie, for sharing that.
23 Thanks. Jackie, let me turn to you. Are you ready to
24 share your experiences?

25 MS. LUCIANO: Yes. Can you hear me okay?

1 MS. BENT: Yes, I can. Thank you.

2 MS. LUCIANO: Great. All right. Thank you,
3 Robyn, for the introduction and to the FDA for inviting
4 me to be here to share my perspective. I'm a current
5 long hauler since January 2022 and have complex
6 associated conditions such as dysautonomia, POTS and
7 suspected myalgic encephalomyelitis. I had to put my
8 career on hold as a regulatory nurse consultant. I
9 suffer daily from several symptoms of long COVID, and
10 finding treatment for these symptoms has been an
11 insurmountable challenge.

12 I've been bounced around over a dozen
13 specialists and was often refused treatment because they
14 were either not FDA approved for long COVID, blood work
15 was normal or there are not enough studies. Initially,
16 I was prescribed daily exercise, and I learned the hard
17 way that this caused harm, and I've been suffering the
18 consequences since then. Thanks to advocacy groups such
19 as MEAction and Long COVID Justice, I learned what post-
20 exertional malaise is and tips on how to stop, rest and
21 pace, which I must continue to do every day because,
22 yes, exercise still causes me harm now.

23 By October 2022, I couldn't complete rehab due
24 to the post-exertional malaise, and I was still being
25 prescribed more medications despite taking over 30 pills

1 a day, and kept having adverse effects. During an ER
2 visit for an acute flare, I was appalled that I was
3 treated inhumanely by healthcare staff, and I'm
4 disgusted by how the medical system is still failing
5 patients. Thanks to a wonderful online community who
6 have shared their experiences with complex conditions, I
7 have learned about and tried various interventions,
8 noting that what has worked for others may or may not
9 work for me and vice versa.

10 Partnering with providers who believe me, who
11 keep up with the latest research and who help me
12 prioritize treatments for viral clearance, sleep,
13 dysautonomia, hormonal balance and staying within my
14 energy envelope have allowed me to better manage my
15 symptoms and activate my body's innate ability to heal.
16 Examples include vagus nerve stimulation,
17 neurobiofeedback, mitochondria and neuroimmune infection
18 control supplements. I started avoiding dairy and
19 gluten to decrease inflammation and reintroduce
20 massages, acupuncture and chiropractic care to help with
21 lymphatic drainage, circulation and pain management.

22 I also have to pay for IV hydration and
23 electrolyte replacement at private clinics to prevent ER
24 visits. I weaned off of several prescribed medications
25 because I was either getting more side effects or I no

1 longer needed them. But I do continue on hormone
2 replacement therapy, antihistamines, midodrine and
3 supplements. There's been a lot of trial and error, and
4 thankfully I am currently sleeping better and have
5 improved blood flow. But I still experience fluctuating
6 disabling symptoms. Thus, all of the above are still
7 not enough.

8 We need an operation warp speed for
9 diagnostics and treatments for long COVID and associated
10 conditions. Treatments need to address inflammation,
11 viral persistence and reactivation, immune system
12 dysregulation, hypoperfusion, mast cells, hormonal
13 imbalances, menstrual cycles, microclots, cognitive gut,
14 autonomic dysfunction and more. Each person is unique;
15 therefore, treatment plans must be individualized and in
16 addition to addressing the root physiological causes of
17 symptoms, the overall goals must be to safely improve
18 one's functional baseline and quality of life as many of
19 us are still grieving our former selves.

20 I'm grateful to have access to a range of
21 providers, but I wish care was accessible and affordable
22 to all who need it. The best resources and information
23 are from the patient community, who generously use their
24 scant energy for the benefit of others. The information
25 we need has not been available by government agencies

1 nor the medical establishment, and I was one of those
2 nurses, but not anymore. In collaboration with fellow
3 long haulers and allies, we started a global toolkit to
4 help empower patients and caregivers to provide hope and
5 to remind everyone not to give up. Stay tuned. Thank
6 you so much for recognizing us patients with lived
7 experiences as experts and how post-infection associated
8 conditions can no longer be ignored. Together, we will
9 make a difference. Thank you.

10 MS. BENT: Thank you, Jackie. Really, really
11 appreciate you sharing your experiences. Let me turn
12 now to Daniel. Daniel, if you want to go ahead and
13 share your experiences, we would very much appreciate
14 it.

15 MR. LEWIS: Thank you, Robyn. When long COVID
16 has taken everything from you, your money, your job and
17 career, and all your goals in life, when long COVID has
18 taken your appetite, your sleep, your breath, your
19 comfort in your own body, your ability to stand or move,
20 your balance and your memories, when it's taken your
21 whole life outside your home, your sense of belonging,
22 your dreams for the future, your independence, your
23 dignity, your security and your freedom, all you have
24 left is hope that research into treatments will deliver
25 you from immiseration and your unthinkable fear that you

1 will never get better.

2 We need safe treatment options now. Three
3 years have passed. Over a billion dollars has been
4 spent on research without producing a single approved
5 treatment. Hundreds of billions of dollars have been
6 spent on healthcare and hundreds of billions more on
7 lost productivity, lost wages and disability.

8 We have experienced unfathomable suffering and
9 loss. We do not have three more years. We will not
10 survive three more years. I have seen countless doctors
11 and taken over a dozen different medications, but they
12 are all for symptom management or they're ridiculous
13 long shots, nothing that we expected to heal me and none
14 of them has fundamentally improved my condition. And
15 nothing can manage my most disabling symptoms related to
16 exertion.

17 I take a beta blocker and midodrine for POTS
18 and Bupropion for fatigue. They are the only things I
19 have found that help at all. And they only help a tiny
20 bit. I am missing work and I can't access disability
21 benefits. I am missing weddings and bat mitzvahs and
22 holidays. I am missing time with my family, friends and
23 community. I am missing my chance to get married and
24 start a family. I have lost over ten pounds and my
25 muscle mass is depleted. I am literally wasting away.

1 This is a matter of life and death for many, and for the
2 rest of us, it is a matter of life and a life so
3 circumscribed by disability and pain that it's hardly a
4 life at all.

5 We need safe treatment options now. Trial
6 ambitious new treatments that modify this disease and
7 give us a fighting chance at recovery. Launch new
8 clinical trials today. We are waiting for our chance to
9 try sulodexide, Ampligen, Inspiritol, temelimab,
10 ibudilast, BC 007, RSLV-132 and many other drugs still
11 in development. Use crossover trials, expanded access,
12 emergency use authorization, accelerated approval, fast
13 track all the tools at your disposal to get these
14 potentially lifesaving treatments to patients.

15 And while we wait for novel treatments we need
16 to be able to try antivirals for COVID, antivirals for
17 reactivated viruses, JAK/STAT inhibitors, anticoagulants
18 and antiplatelets, metformin, combination maraviroc and
19 pravastatin, and all the other drugs that already have
20 FDA approval and have shown promise in early research
21 but are still hard to get.

22 Both primary care physicians and specialists
23 don't know what to do with us. Doctors need clear and
24 direct clinical guidance to prescribe these potentially
25 lifesaving treatments to patients.

1 This illness is defined by loss, and we are
2 losing everything, even our memories and our sense of
3 who we are. We are hanging on by a thread. That thread
4 is the hope that things will change, that the NIH will
5 fund clinical trials for ambitious long COVID
6 treatments, that researchers will understand long
7 COVID's disease process and how to interrupt it, that
8 drug manufacturers will recognize that if the U.S. has
9 already spent over half a trillion dollars on medical
10 expenses related to long COVID, then we'd be willing to
11 spend a hell of a lot more than that on a treatment that
12 works, that the FDA will authorize promising long COVID
13 treatments without delay, that clinicians will treat
14 their patients with compassion and urgency,
15 administering treatments ethically and equitably, that
16 patients will have the treatments they need to live and
17 that we will be so successful that we can use America's
18 response to long COVID as a model for how the world
19 should treat all patients with debilitating chronic
20 illnesses. Thank you.

21 MS. BENT: Thank you, Daniel. Let us now turn
22 to Tammy to hear some of your experiences. Tammy?

23 MS. WILSHIRE: Hi. Good afternoon. My name
24 is Tammy Wilshire. I became a COVID long hauler as a
25 result of a March 2020 initial infection. My

1 experience, especially in regards to seeking treatment
2 options, is a long and very complex story.

3 I think it is important to mention that I am a
4 resident of a small rural farming and coal mining
5 community in the west central Appalachian Mountains of
6 Pennsylvania. Due to this, my access to care was and
7 still is very limited; therefore, my biggest challenge
8 to receiving proper treatment.

9 Early in the pandemic, we did not have access
10 to COVID testing here. As a result, I found that a
11 presumptive positive test did not allow me to take
12 advantage of a lot of the care clinics and treatments
13 that later became available. My treatment is a
14 continually evolving plan. We put out the major fires
15 such as cardiac issues and endocrine issues, while
16 ignoring the other more minor fires, such as
17 neurological issues and pain management. I had to deal
18 with most of these things myself, with some help from my
19 caring but overwhelmed primary care physician.

20 Even when I was hospitalized with cardiac
21 issues in July of 2020, I heard frequently it must be
22 anxiety, and I was not taken seriously. It took me
23 almost 18 months to begin to find help, mostly through
24 specialty doctors over two hours away, and through long
25 COVID groups online. To date, I have tried physical

1 therapy, supplements like vitamin C, D3, B12 and
2 magnesium, beta blockers for my tachycardia, gabapentin
3 and other neuro meds for the tremors and the worsening
4 fibromyalgia, statins for increased cholesterol and
5 vascular inflammation from COVID, pain creams, muscle
6 relaxers, anti-nausea and GERD medications and more with
7 just limited success.

8 Of these treatments, I initially had the most
9 success with physical therapy. I saw an improvement in
10 my stamina/strength and in my POTS heart rate. However,
11 after about two weeks, as we added more exercises, I
12 began to feel a lot worse. My ME/CFS relapsed with
13 crippling fatigue. After PT, I would find myself
14 needing to rest. Eventually, I was bedbound again for a
15 day or two following the session due to the post-
16 exertional malaise, and I had to discontinue physical
17 therapy due to exercise intolerance.

18 Due to new endocrine and GI issues, I've had
19 to change my diet to a low carb and anti-inflammatory
20 plan. I have to make time to eat every three hours in
21 order to keep my blood sugar stable. This requires
22 quite a lot of effort and planning while balancing my
23 energy levels, and it still isn't completely solving
24 these issues for me.

25 I would 100 percent say that my long COVID is

1 not well-managed at this time. After three years and
2 two probable COVID infections, I am just now being
3 examined by specialists for issues that started in 2020.
4 The dynamics of my symptom presentation have definitely
5 changed. Some things have gotten better on their own or
6 with some medical management, but I still suffer with
7 quite a lot of symptoms that are not well-controlled
8 for various reasons.

9 I fully suspect that there will be no one size
10 fits all cure for long COVID. Each individual is unique
11 in their presentations and their symptoms. However,
12 just an improvement in pain relief and fatigue would be
13 amazing. Thank you for allowing me to share a small
14 part of my long COVID journey with you today.

15 MS. BENT: Thank you, Tammy. Thank you for
16 sharing that with us. And for our final panelist, we're
17 going to hear from Angela.

18 Angela, if you want to go ahead.

19 MS. VAZQUEZ: Great. Thank you so much. And
20 thank you to the FDA for hosting this important forum on
21 long COVID. My name is Angela M. Vazquez and I am
22 president of Body Politic, a grassroots health justice
23 organization and home to one of the first global COVID-
24 19 patient support groups.

25 Before getting COVID here in Los Angeles in

1 March 2020, I was a runner for nearly two decades. What
2 started as a mild illness progressed over weeks with an
3 increasingly scary set of symptoms including severe
4 blood clots, a series of mini strokes, brain swelling,
5 seizures, painful heart palpitations, severe shortness
6 of breath, extreme confusion and numbness in my face,
7 hands and legs that progressed to an inability to walk
8 for several days and new onset of anaphylaxis. All of
9 these were largely untreated and not even acknowledged
10 by physicians for nearly a year.

11 So the first thing I would like to emphasize
12 is that long COVID patients from the first and second
13 waves of the pandemic had a fundamentally different
14 trajectory than those who came after us. Just because
15 we weren't hospitalized does not mean we shouldn't have
16 been. In fact, we experienced severe but unaddressed
17 symptoms in 2020 and also come from communities of
18 color, represent some of the sickest and most medically
19 marginalized patients that deserve urgent specific
20 treatment and prioritized access to clinical trials.

21 With long COVID, I now have several chronic
22 conditions, including ME/CFS. My most debilitating
23 symptom is known as post-exertional malaise, but which I
24 experience as post-exertion neuroimmune dysregulation.
25 My PEM is composed of my worst symptoms like insomnia,

1 cognitive dysfunction and confusion, sleep apnea, heart
2 palpitations, fevers and chills, severe migraines, joint
3 and muscle pain, invisible tremors and muscle jerks. I
4 have developed a strict pacing regimen that allows me to
5 work from home full-time but not do much else.

6 My long COVID conditions (indiscernible)
7 others come out to play in short order. I take 15
8 different medications regularly, many several times a
9 day, and most to manage my mast cell activation and
10 autoimmune inflammation. I also get weekly four hour
11 Benadryl and saline infusions. I'm on a number of
12 expensive supplements to support my mitochondrial
13 health, and I also now have severe joint and nerve pain
14 in my neck and face, and an MRI has shown marked disc
15 degeneration in my neck.

16 My doctors suspect that long COVID triggered
17 inflammatory arthritis in my cervical spine and could be
18 driving many of my neuroimmune symptoms, something I've
19 learned is not uncommon for patients like me with
20 inherited or acquired connective tissue disorders. I am
21 currently exploring regenerative medicine options for my
22 neck, as physical therapy has only been marginally
23 effective. None of these treatments address the core
24 drivers of my long COVID.

25 One of the biggest ongoing barriers to getting

1 treatment is the lack of providers knowledgeable about
2 infection-associated chronic conditions who can make
3 accurate clinical diagnoses and develop a coherent
4 treatment plan.

5 I highly recommend clinical trials not base
6 their cohorts exclusively on diagnosis-based conditions,
7 but also include symptom clusters that reflect the
8 evolving knowledge of these conditions, so those who
9 lack access to knowledgeable providers, especially low
10 income people of color, are not excluded from treatment
11 trials.

12 Finally, I was also recently reinfected and I
13 was lucky enough to get an extended course of Paxlovid
14 for 15 days per the clinical trials for long COVID. My
15 conditions flared quite extensively for several weeks
16 and my post-exertion malaise is now much more prominent.
17 I highly recommend clinical trials build in protocols to
18 manage worsening of symptoms, especially when treating
19 chronic infections. For example, chronic Lyme disease
20 patients (indiscernible) regarding what is
21 (indiscernible) to antibiotic treatment. Despite an
22 extended flare, Paxlovid seems to have prevented a
23 significant (indiscernible) in my cognitive dysfunction
24 and also seems to have eased my gastrointestinal issues.
25 The gut-brain axis of mutually reinforcing inflammation

1 appears key for me. I was also one of the few who
2 improved after my first vaccine. So I am very
3 interested in how treating persistent or reactivated
4 infections could impact my long COVID.

5 So I'll close with saying that my request to
6 treatment developers (indiscernible) please focus on
7 this thing called post-exertion malaise. While each
8 person's malaise may look different, it follows a unique
9 and distinct pattern across patients who have it. We
10 need to know how it relates to mast cell activation and
11 blood clots, orthostatic intolerance and blood flow to
12 the brain and nervous system, how persistent infections
13 exhaust the immune system and erode connective tissue
14 surrounding the spinal cord. The answers are there. We
15 just have to look at the body much more globally than we
16 ever (indiscernible).

17 MS. BENT: Thank you, Angela. So, once again,
18 those are some really compelling and diverse
19 experiences, and I want to thank all of our panelists,
20 Stephanie, Jackie, Daniel, Tammy and Angela for sharing
21 their experiences.

22 So at this point, maybe let me turn to my
23 colleagues, FDA and HHS colleagues, to see if we have
24 any clarifying questions for the panelists before we
25 turn to some of the callers that we have. So

1 colleagues, I don't know if you have any questions. If
2 not, maybe we can turn back to you after we take a few
3 calls from the callers. All right. I don't see that we
4 have any clarifying questions, which I think is a
5 testament to how clearly everybody was able to share
6 their experiences.

7 So let me then turn to our callers online.
8 Let me start with Sawyer on line one.

9 LARGE-GROUP FACILITATED DISCUSSION ON TOPIC 2

10 SAWYER: Hello. Can you hear me?

11 MS. BENT: Yes, I can. And before you get
12 started, there's a little bit of a challenge for our
13 interpreters with the phone clarity. So if you would be
14 willing to just speak slowly and clearly to help
15 optimize our chances of successful interpretation, I'd
16 really appreciate that.

17 MR. BLATZ: Yeah, definitely.

18 MS. BENT: Thank you.

19 MR. BLATZ: Yeah. So I'm Sawyer Blatz. I was
20 a previously healthy and extremely active 26 year old.
21 Long COVID has been devastating and life ruining for me
22 since my first mild infection in November of 2022. I
23 eat a healthy diet, worked out five times a week, was
24 recently boosted and had no preexisting conditions. I
25 have lost my work, my ability to leave the house, my

1 ability to run and weightlift and even simple things
2 like being able to shower daily or cook meals for
3 myself. It's safe to say that in my current state, my
4 long COVID is not well-managed, despite lots of
5 attempted interventions.

6 My worst symptoms are crushing fatigue, POTS,
7 cognitive dysfunction and insomnia. These symptoms have
8 resulted in me being almost entirely bedbound and my
9 partner being my full-time caretaker. All of my
10 symptoms are worsened by exertion and can lead to
11 crashes. On my worst days, suicidal ideation is
12 constant, and the immense grief I've experienced from
13 the full life I can no longer live is crushing.

14 My current treatment course is trying to
15 address reactivated viruses like Epstein-Barr virus,
16 which I tested positive for, with antivirals like
17 valacyclovir. It's too early to say if this is helping
18 me, as it could take months for it to have an effect.
19 But it has shown promising results for some folks with
20 ME/CFS.

21 We desperately need the FDA to help expedite
22 research into treatments that solve the underlying
23 pathology of long COVID, not just symptom management.
24 And when promising interventions are found, we need them
25 to be authorized with emergency approval. Treatments

1 specifically looking into post-exertional malaise and
2 orthostatic intolerance like POTS are of intense
3 interest to me. Myself and millions of others have lost
4 our lives to this disease. Please take our suffering
5 seriously. Thank you for your time.

6 MS. BENT: Thank you, Sawyer. Let me now turn
7 to, let me see, Maria on line five.

8 MARIA: Hi. Yes.

9 MS. BENT: Thanks. Go ahead, Maria, if you
10 want to talk to us a little bit about what you're
11 currently doing to treat or manage your long COVID, and
12 if that regimen has changed over time at all, that would
13 also be really helpful for us to know.

14 MARIA: Yeah, absolutely. I am a formerly
15 healthy 31-year-old woman with long COVID from my first
16 infection. Currently, my routine includes prioritizing
17 rest, avoiding inflammation and taking a variety of
18 supplements and sort of natural herbal teas and foods to
19 either treat my symptoms or attempt to address the root
20 cause of my long COVID based on hypotheses I or other
21 patients have developed. I avoid exercise, stress and
22 situations where I might be reinfected to the detriment
23 of my social life and my career.

24 I manage my long COVID decently well, but
25 constantly fear that I will deteriorate and will not be

1 able to recover. Unlike many of my peers and my medical
2 providers, I am well-aware of the risks of long COVID.
3 I've had multiple doctors tell me that my fatigue and my
4 inappropriately high heart rate are the result of
5 deconditioning, despite having been an athlete for my
6 entire life, had a cardiologist tell me that I should
7 not exercise, and then later revised that to say that I
8 should. She would not prescribe me any medications and
9 did not have other suggestions on how to address my
10 vascular symptoms.

11 At this point, every day I eat fermented foods
12 like natto and take nattokinase and serrapeptase
13 supplements, which I learned about online. There's a
14 strong community of long COVID patients, and I've
15 learned more there than from any single doctor. Those
16 supplements are known for their abilities to break down
17 fibrin and proteins and blood clots. This markedly
18 improved my energy and helped against fatigue, but
19 seemed to have an upper limit of effectiveness. I
20 informed my cardiologist about this and the supplement's
21 anticoagulation qualities, not the other way around, as
22 it should have been.

23 I'm self-treating on the assumption that I
24 have microclots and inflammation in my vascular system
25 and possibly a lingering infection. But without medical

1 supervision, I know I need to be cautious about other
2 risks. I have read that triple anticoagulant therapies
3 are fruitful for some patients, but working alone, I
4 can't risk causing other health problems by thinning my
5 blood too much. I have no medical team with which to
6 pursue a more aggressive therapy, and as I never had a
7 positive PCR test, I can't get into long COVID clinics
8 or clinical trials.

9 I prioritize rest, which my doctors have not
10 even recommended, but I know from other long COVID
11 patients that can be crucial to recovery. In addition
12 to the first supplements I mentioned, I take coenzyme
13 Q10, a variety of B vitamins, vitamin C, magnesium and
14 vitamin D, which I was already taking as I've been
15 deficient in the past.

16 My PCP ran many blood tests at my request,
17 which turned up abnormalities like elevated lipids,
18 including triglycerides and cholesterol, which has
19 always been on the low side for me, but offered me no
20 follow-up care or explanation for those abnormalities or
21 concern for these new unhealthy markers. I was already
22 aware that these are possible results of a COVID
23 infection, though I don't know the mechanism for this
24 metabolic change or how to reverse it when I already
25 have a clean diet and cannot exercise.

1 My primary care provider did not even remark
2 on this change in my health or suggest rudimentary
3 improvement. I was also screened for autoimmune markers
4 but received no feedback on these results. Again, after
5 listening to other patients, I'm working to reduce
6 inflammation in my body in the hope that my symptoms are
7 partially caused by a positive feedback loop that I
8 might (indiscernible) out of. What if that inflammation
9 is serving some important purpose, like fighting a
10 lingering infection? I don't have anyone to guide me,
11 and I worry that I will prolong my recovery by trying
12 the wrong tactic.

13 I also have test results suggesting viral
14 persistence of herpes viruses, but my PCP has not
15 connected those to my current status. I'm weighing the
16 risk of reinfection via additional visits to a facility
17 with no mask mandates in order to suggest antiviral
18 medications. As I've read online and we've heard from
19 other callers, that that has helped other patients, but
20 I feel as though I'm the one piloting my care when
21 acclaimed medical facilities in a major city should have
22 experts to guide me.

23 I've also read about stellate ganglion blocks
24 and existing treatment to reset dysfunction in the
25 autonomic nervous system. Many of my symptoms, like

1 inappropriately high heart rate and breathing issues
2 point towards this system as the root of my problems,
3 but no doctor has given me any assistance on how to
4 modulate my nervous system or improve my health there.
5 I could pursue a stellate ganglion block on my own time
6 and through a private practice, but I might just be
7 scammed, or I might come up with worse health in the
8 end. Many patients report success with this off-label
9 application of the procedure, but there's little
10 research on whether it's an appropriate treatment,
11 whether it's a risk or a waste.

12 I'm frustrated that I keep coming up with
13 series of hypothetical treatment plans for myself
14 instead of getting personalized, effective care from
15 trained professionals. I've also read about the
16 potential of the Novavax vaccine to succeed where mRNA
17 vaccines have begun to fail, but I cannot access it. I
18 only hear about its potential from the long COVID
19 community, not medical outreach or PSAs aimed at
20 vulnerable populations.

21 With my current long COVID, I'm scared that an
22 additional mRNA booster might lead to an increase in
23 symptoms, as some patients report, though others do see
24 improvements. It feels like a roll of the dice, and for
25 a vaccine that's less protective against each new

1 variant anyway. I would like to see Novavax as an
2 option for vaccination. And if I'm taking my healthcare
3 decisions into my own hands, I would at least like to be
4 able to act on the research that I read. I have read a
5 variety of hypotheses.

6 MS. BENT: Thank you. Thank you, Maria. I'm
7 going to ask you maybe to just focus on maybe one or
8 more two more quick, quick points, because we do need to
9 move on to other callers as well.

10 MARIA: Sure.

11 MS. BENT: Please go ahead. Thank you.

12 MARIA: In general, I'm an intelligent and
13 highly educated person, and I'm comfortable weeding out
14 pseudoscience and misinformation, and I'm open to advice
15 from outside the medical system. But as many patient
16 research projects and hypotheses are proving correct,
17 from the existence of long COVID itself to mechanisms
18 like microclots in the blood and viral persistence, we
19 are exhausting ourselves spending so much time, effort
20 and money in search of cures that could be more
21 efficiently found, tested and publicized by major
22 medical establishments.

23 I hope some of the topics that I mentioned
24 here will be picked up and fast-tracked, as they seem to
25 have potential. But as a study of one, no patient

1 should have to be testing theory after theory on
2 themselves in hopes of leading a healthy life. Thank
3 you.

4 MS. BENT: Thank you. Let me turn to
5 Christine on line ten.

6 CHRISTINE: Great.

7 MS. BENT: Hi, Christine. I know you're a
8 little bit faint, so is there any way we can -- let's
9 see.

10 CHRISTINE: Oh, is it any better?

11 MS. BENT: Yes, that is much better.

12 CHRISTINE: Okay. Okay.

13 MS. BENT: All right, please --

14 CHRISTINE: Please let me know if it fades out
15 again.

16 MS. BENT: Okay. I will do. And I know we
17 have a good number of people on the line, so I'm going
18 to ask you to maybe just keep your comments to two or
19 three minutes. Thank you so much.

20 CHRISTINE: Absolutely. Yeah. I was asked to
21 comment. I'll be commenting on my treatments and then
22 the symptoms that I'd like to see prioritized. So I
23 first had COVID in November of 2020 prior to
24 vaccinations. I've had long COVID for two years, since
25 March of '21. It started at the moment I had my second

1 COVID vaccine. I had an anaphylactic reaction to the
2 Pfizer vaccine, and then that -- all the antibodies
3 mixing fired off, everything I deal with now. So my
4 therapies treat, Band-Aid, suppress or help me cope with
5 my long COVID. I have not reached a point of an
6 optimized functional life. Part of my treatment
7 includes prescription, over-the-counter medications and
8 supplements. I use methylphenidate, which is Ritalin
9 and naltrexone, and those are both off label for long
10 COVID, which means we pay out of pocket for those.

11 The methylphenidate was prescribed for POTS,
12 but that Ritalin actually helps my brain fog and mental
13 clarity much more. The naltrexone is for inflammation,
14 and that is very helpful. I receive saline infusions
15 twice a week for my POTS diagnosis. That is very
16 helpful. It gives me much more focus and energy on
17 infusion days. The saline increases my plasma so the
18 blood moves more independently, kind of like a lava lamp
19 through my body.

20 I have participated in occupational therapy.
21 The purpose of that was for energy conservation. I got
22 connected with TheraSpecs prescription, fluorescent, UV
23 and blue light filtering glasses, which are a godsend
24 for the light intolerance. I have participated in
25 speech therapy for the brain fog, word recall, memory.

1 It's given me permission to tell people I need a pause.
2 These therapists didn't have a long COVID protocol, so
3 they used traumatic brain injury and stroke protocols,
4 which I responded to.

5 I did pulmonary therapy, but I was not able to
6 reach the goals because of exercise intolerance. I made
7 it through about eight sessions. I was doing 16
8 sessions on a recumbent -- or 16 minutes on a recumbent
9 bike. I went to 18 minutes. At the end of that 18-
10 minute session at a very, very low exertion rate, I
11 stood up and had intense bout of syncope. So I have not
12 completed pulmonary therapy.

13 When I am more stable, I will do vestibular
14 therapy and physical therapies for balance, stability,
15 coordination and strength. I wear a digital medical ID
16 bracelet because when I have my syncope episodes, I also
17 have seizure-like activity and I'm unresponsive for 15
18 to 90 minutes. So that bracelet has a QR code on it,
19 and anyone with a phone can access my important
20 information when I can't speak for myself.

21 I'll start counseling services next week
22 because the reality of living with this, as everyone has
23 said, is devastating, and it's very likely that I will
24 not be able to return to elementary teaching next school
25 year. I use a Fitbit to monitor my heart rate with my

1 POTS. I use meditation as a form of mental and physical
2 relaxation. If I can walk a little bit outside, I do,
3 or I just sit outside. I've started using noise-
4 canceling earbuds for sound sensitivity so that I can
5 participate in life a little bit. So those are my
6 treatment plans.

7 The particular symptoms of long COVID that I
8 prioritize for treatment are my intense nervous system
9 issues, which include syncope with seizure-like activity
10 that happens several times a month and then presyncope
11 symptoms, nerve damage, vertigo, fatigue, hyperhistamine
12 reactions, the brain fog and neuropathic POTS. So
13 that's all of my information. Thank you for listening
14 to me.

15 MS. BENT: Thank you, Christine. Really
16 appreciate you calling in and sharing that and really
17 speaking to the specific question that I asked, so I
18 really appreciate that. Thanks. So we're going to take
19 one more call right now, and then we're going to move on
20 to some polling questions. Let me turn to Carly on line
21 11.

22 CARLY: Hi, can you hear me?

23 MS. BENT: Hi, Carly. Yes, I can hear you.

24 CARLY: I'm going to try to make this as brief
25 as possible.

1 MS. BENT: Thank you. Brief, but speaking
2 slowly, right?

3 CARLY: That's right. I have all the POTS,
4 ME/CFS, chronic fatigue stuff that you have heard over
5 and over again. I was initially infected in October of
6 2020, and my first long COVID complication resulted in
7 hospitalization in January of 2021, approximately eight
8 to nine weeks later. I was admitted to ICU with
9 exceptionally unstable vital signs and I was treated for
10 migraines, and I believe it was coded as a migraine
11 admission. I had a history of chronic migraines prior
12 to my COVID infection and was undergoing many treatments
13 for that, but it was well-controlled.

14 The summer before I contracted COVID, I was on
15 a boat every weekend, staring at glares on the water,
16 rocking back and forth, drinking cocktails. None of
17 that is possible now. In addition to hospitalization,
18 every year I participate in physical therapy,
19 occupational therapy and home health services to rehab
20 myself back to my disabled baseline after
21 hospitalization. I have annual surgical ablations to
22 treat migraines. Additionally, I take many medications
23 for migraines. I'm not going to list them all. Lots of
24 medications, lots of dietary supplements.

25 Some of these treatments have caused elevated

1 liver function tests and I've had to stop them. I take
2 so much Zofran, it gives me serotonin syndrome.
3 Seriously, I'm a zombie because I take Zofran. It's
4 ridiculous. My POTS and heart failure with preserved
5 ejection fraction that was diagnosed by double right
6 heart catheterization is treated with metoprolol,
7 spironolactone, Jardiance, 6,000 milligrams of sodium
8 daily and electrolyte drinks.

9 I use a mobility aid, trekking poles for
10 walking, and a shower chair with a handheld shower
11 nozzle. I take three antidepressants for depression and
12 sleep. Notably, on my last hospitalization, I was also
13 suicidal due to the fact that I was so terribly sick.
14 As soon as they treated my electrolyte imbalance, the
15 suicidal ideation went away.

16 I am to begin pulmonary rehab in June, as I
17 have just last week completed my first appointment with
18 a long COVID provider. I have moderate lung disease and
19 I'm going to start the pulmonary rehab and the Dulera.
20 I also take medicine for tremors. I would not say my
21 COVID is well-managed because my POTS symptoms and my
22 migraine symptoms keep me parked on the couch. I don't
23 go outside. I don't go on dates. I don't go out to
24 eat. I don't go visit my friends. So no, being shut in
25 is not well-managed.

1 Prior to COVID, I was a 43-year-old, very
2 active hiker, paddle boarder, bicyclist, even did a
3 sprint triathlon at one point in the not too long past
4 history, and now I am completely unable to exercise.
5 The things I would look for in an ideal treatment would
6 be treatment for brain fog, fatigue and temperature
7 intolerance. Those are my most limiting symptoms that
8 impair my ability to even pursue hobbies. Thank you so
9 much for giving me the time to share my story.

10 MS. BENT: And thank you, Carly, for sharing
11 your story. We really appreciate that. So we are going
12 to turn back to callers in a few minutes, but first
13 we're going to move on to some polling questions to get
14 feedback from all of you who are joining us online.
15 Polling does remain limited to participants who have
16 lived experiences with long COVID, either personal
17 experiences or as family members and loved ones. And so
18 now we're going to move on to questions for topic two.

19 The first question is currently there are no
20 medical products approved for treatment of long COVID.
21 However, some treatments have been used off label.
22 Which of the following medical products, that includes
23 drug therapies or medical devices or interventions, have
24 you used to treat the symptoms of your long COVID?
25 Please check all that apply. And this includes --

1 sorry, apologies. Answers are, A, antidepressants; B,
2 sleep aids; C, antivirals; D, antihistamines; F,
3 analgesics, pain medicines such as acetaminophen or
4 NSAID, so Tylenol or Motrin or things like that; G,
5 corticosteroids such as dexamethasone, prednisone or
6 cortisone; H, medical devices or other procedures; and
7 I, other.

8 So it looks like we're seeing a lot of use of
9 all of the different categories that we listed here.
10 We're seeing -- it's hard to tell. It looks like the
11 antihistamines, the Benadryl or diphenhydramine are one
12 that is largely used by the group, some medical devices,
13 analgesics, pain medicines. So, yeah, it looks like
14 there's a lot of use of all of these categories of
15 medicines across the board.

16 Is it possible for us to go back and show
17 people the QR code one more time? I feel like maybe we
18 didn't show that recently, so our participants for
19 session two might not have necessarily access to that.
20 Okay. Great. So it's being shown on the screen in the
21 video feed, so you all should be able to see the QR code
22 there if you need that to access the poll. Thank you.

23 All right. Let's move on to our next
24 question. Which of the following interventions have you
25 ever used to manage the symptoms related to your long

1 COVID? Please check all that apply: A, pulmonary
2 rehabilitation or aerobic exercises; B, vitamins, herbal
3 supplements or dietary supplements; C, diet
4 modifications; D, meditation; E, acupuncture; F,
5 physical or occupational therapy or rehabilitation; G,
6 psychological or cognitive behavioral therapy; H, other;
7 or I, none of the above.

8 All right. And looking at this, we're seeing
9 a good number of people have been using both meditation
10 and dietary modifications, as well as vitamins, herbal
11 supplements and dietary supplements. We see a number of
12 people who have been able to take advantage of physical
13 or occupational therapy or rehabilitation. All right.
14 And a good number of people, 12 percent of people who
15 are saying other. And so that's also helpful for us to
16 know.

17 Maybe while we're waiting for these results to
18 come in, I can turn to Shannon to see do we have any
19 themes about treatment options or any comments that
20 you've been receiving related to treatment options,
21 Shannon?

22 MS. SPARKLIN: Yes. Thank you, Robyn. We've
23 received several written comments related to treatment
24 options, many of which are reflective of what the
25 panelists shared earlier. But just to list a few,

1 there's a wide range of prescription medications, over-
2 the-counter medications, as well as other therapy
3 options that commenters have used. Just to list a few,
4 they've listed ibuprofen, Trazodone, Lexapro,
5 riboflavin, prednisone, antibiotics, low-dose
6 naltrexone, low-dose Abilify, Novavax, Amplogen, beta
7 blockers. And then in terms of alternative therapies,
8 commenters have mentioned acupuncture, enhanced external
9 counterpulsation or EECF therapy. They've also
10 discussed nutritional supplements, ginger, physical
11 therapy, rest and pacing, and vitamins and other
12 supplements.

13 And overall, another theme that I'm seeing in
14 the written comments is regarding a difficulty with
15 accessing medication and treatment options due to
16 doctors or physicians not believing their symptoms or
17 not knowing how to treat them or lack of diagnosis.
18 Thank you.

19 MS. BENT: Thanks, Shannon. Really, really
20 appreciate that. And so looking at the responses from
21 both the prior question and the current question, I
22 think we can see that a lot of people have tried a lot
23 of different treatments.

24 And so I'm going to turn now back to some of
25 our phone callers to see maybe if they can talk with us

1 a little bit about any medications that they've tried.
2 What aspects of long COVID do their medications address
3 well, and what aspects do they not address well? And so
4 let me turn to Rebecca in Georgia or on line one to kind
5 of share with us maybe her thoughts.

6 REBECCA: Hi, can you hear me?

7 MS. BENT: Hi. Yes, Rebecca. Is this
8 Rebecca?

9 REBECCA: Yes.

10 MS. BENT: Yes, we can hear you. And so I was
11 wondering if you would be willing to talk to us a little
12 bit about the different types of treatments that you've
13 tried, particularly medicines, if they've addressed any
14 aspects of long COVID or maybe if there are any aspects
15 that they do not address. And I would just ask you
16 because we do have a number of people calling to keep
17 your comments relatively brief, but also to speak
18 slowly.

19 REBECCA: Okay. Well, just try to bear with
20 me a little bit. I have some communication issues.
21 I've had some strokes after COVID.

22 MS. BENT: Okay.

23 REBECCA: So bear with me a little bit because
24 I do stutter a little bit and slur my words a little.
25 So bear with me a little.

1 MS. BENT: That's fine. We're more than
2 willing to bear with you. We appreciate you calling.
3 So thank you.

4 REBECCA: Thank you. So I got COVID in
5 February of 2020. I was a healthcare worker, and so I
6 got it in February of 2020, and I first developed long
7 COVID over spring of 2020. I guess by July, I was first
8 hospitalized in October, and then by February of '21, I
9 had my first stroke. Sorry, I'm trying to quickly get
10 to my point here. Over the course of '21, I was
11 hospitalized numerous times, and where it was found that
12 I had multisystemic organ damage, my lungs, my
13 gastrointestinal system, my gallbladder. I had lung
14 damage, brain damage. So I had different areas. I had
15 developed cardiac conditions. I had no cardiac
16 conditions prior, no pulmonary conditions prior to
17 COVID. I developed asthma, post-viral-induced asthma.
18 I am now on six inhaler treatments and four breathing
19 treatments a day from my asthma that I got from COVID.
20 I now have to take two different blood pressure. I have
21 stage three hypertension from COVID. I have significant
22 amount of brain damage. I have damage to my frontal
23 lobe, my basal ganglia and my right parietal lobe. I
24 have lesions throughout my brain and my brain stem. And
25 I have also developed four brain aneurysms, which are

1 inoperable unfortunately.

2 Unfortunately, the majority of this is because
3 of my cardiac conditions that developed from COVID and
4 then not being treated, going unchecked because I tried
5 to get into long COVID clinics, and even after being
6 listed as a long COVID patient, I couldn't find a long
7 COVID clinic in my area that would accept me. I
8 couldn't get -- even now, even though I'm listed as a
9 long COVID patient on all of my -- I'm diagnosed as a
10 long COVID patient, and it's on all of my charts. I'm
11 not being treated anywhere as a long COVID patient.

12 I'm seeing over a dozen different specialists,
13 but at no point am I being treated as a long COVID
14 patient. I'm not getting any long COVID specific
15 treatments. I'm being treated only for the different
16 types of damages that I have sustained from long COVID,
17 from my pulmonary system, my cardiac system and
18 gastrointestinal system. Everything that I'm getting is
19 only damage specific. Nothing is actually long COVID
20 specific. And that's part of the problem. Long COVID
21 damage has gone unchecked, and it's pretty much I'm only
22 receiving treatment for the damage after it's happened.
23 There hasn't been any treatment happening as it's gone
24 along, even though it's been recognized that what's
25 happening to my body has been as a result of COVID

1 infection.

2 And this has been three years of this
3 happening, and it being recognized by doctors that this
4 is all the result of multiple infections now. And
5 sorry, losing train of thought. And I've now received a
6 potential terminal diagnosis because my brain aneurysms
7 are inoperable and I have clots surrounding them. So my
8 doctors have told me that I could die at any moment, and
9 surgeries probably won't save me if my brain aneurysms
10 do rupture.

11 MS. BENT: That has to be incredibly
12 terrifying. I'm so sorry.

13 REBECCA: Yes. I'm sorry. We desperately
14 need research and treatment for people. I'm sorry. I
15 get very emotional, but we need research for people and
16 treatment because this is me three years into this, and
17 I am day 20 of my fourth infection right now. This is
18 what's going to happen to people if COVID goes unchecked
19 and people don't get the treatments that they need.

20 I'm dying right now because I have not gotten
21 treatment, and this is what's going to happen to
22 millions of people. I am severely disabled. I have
23 severe brain damage. I am bedbound and have to have
24 other people take care of me. I have beginning stages
25 of dementia. I'm 45 years old and can't take care of

1 myself.

2 MS. BENT: Thank you, Rebecca. I really am
3 sorry that you're experiencing this, but I really do
4 appreciate you calling in and kind of sharing this with
5 us because it's important information for us to hear.
6 Let me now turn to Kevin on line three.

7 KEVIN: Thank you very much.

8 MS. BENT: Hi, Kevin.

9 KEVIN: Yeah, thank you very much for having
10 this session with the FDA. I think it's great. It's
11 wonderful to hear so many people calling in and getting
12 those perspectives. I hope you do more of these calls
13 in the future. I'm not going to go into my experiences
14 with long haul COVID. I'm just going to go into
15 treatment.

16 MS. BENT: Thank you.

17 KEVIN: Luckily, I'm blessed. My wife is a
18 physical therapist, so I've got that at home.
19 Acupuncture is another key thing for people to look at
20 for helping with some of these symptoms. But the
21 biggest thing I think anyone should be able to do is
22 find a functional medicine doctor. A lot of the Western
23 medicine took a look at the blood test and they could
24 see problems. They just didn't know how to fix them.
25 I had elevated liver enzymes. I was diagnosed

1 with Hashimoto's thyroiditis, destruction of the thyroid
2 and a number of other things. But it was the functional
3 medicine doctor who actually looked through and got me
4 onto supplements and vitamins. Two of the companies
5 that are ideal are based here in the United States,
6 Optimal Health Systems and Apex Energetics. Both of
7 those companies have stuff, medicines or supplements
8 that can help with reducing some of those post-exercise
9 malaise as well as reducing fatigue. There are B
10 vitamins that can help people. Those are a key thing.

11 The problem, I think, with some of the
12 research that isn't being done is, let's look at these
13 things. Let's look at, rather than try and do some
14 sweeping thing that's going to fix everything, find out
15 what's wrong with people and fix those particular
16 things. So B vitamins can help people make it through
17 the day, vitamin D, vitamin C, melatonin for people to
18 help get through the night. These are key things. I
19 still have the virus inside me. So there's a product,
20 Optiviral, which helps to reduce that and get one
21 healthier. There's Optimal Defense. All these things
22 can help people recover and put those things into check.
23 Some of the things like the Hashimoto's thyroiditis will
24 never truly be fixed. But what I can do is put it into
25 remission. So the key thing is we need more of that

1 research into functional medicine. I think that's the
2 key thing that we're missing.

3 MS. BENT: Thanks, Kevin. That's really
4 helpful. Has your long COVID kind of changed over time?
5 Has it been -- I mean, have you seen -- are you -- or
6 did you -- yeah, let me just stop there.

7 KEVIN: So my long COVID was very
8 debilitating. I had a number of symptoms. One of them
9 included feeling like I had food poisoning every two
10 weeks on the dot, and I would be sick from anywhere from
11 a day to three days not being able to hold down
12 anything. So it was putting some of those things in
13 check and getting some of those liver enzymes. Western
14 medicine doctors were like, all those supplements aren't
15 going to help. A month later, they took a look and
16 they're like, wow, you got your liver enzymes close to
17 normal. It was ten times normal, and you've somehow
18 reduced it in a month.

19 And so those are the key things we need to
20 find functional medicine doctors. That's what we need
21 to start looking at, is putting more research into that,
22 because that was the only way I could put some of these
23 things into check and start to get back to a regular
24 functioning. Yes, there are still some times when if I
25 exert myself way too much, I'll be exhausted. But it is

1 not as bad, thanks to those vitamins and supplements.
2 But they are expensive. So I do spend several hundred
3 dollars every month on vitamins and supplements, but
4 it's the only way to make it through my days right now.

5 MS. BENT: Thank you. Thank you so much. Let
6 me now turn to Tom. Tom, are you on the line? Sorry.
7 I didn't say -- Tom, on line two. Apologies.

8 TOM: Well, so thanks to the FDA for reaching
9 out and listening to the patients. This is obviously a
10 major, major issue in the U.S. and worldwide. Just real
11 briefly, I am kind of in a unique position. I'm a
12 scientist, background in cell biology, molecular
13 biology. I got my PhD in immunology, yet I'm also a
14 long hauler. And so I've been trying my very best to
15 connect all the dots and try to figure out what's going
16 on in my own body personally and with the other
17 suffering long haulers. And I'm currently running --
18 I'm excited to be running a clinical trial called Diet
19 and Fasting for Long COVID. It's a remote trial that
20 people can participate in in the U.S. And it's
21 basically they do their -- alter their diet and do
22 periodic short water fast, and we monitor their overall
23 long COVID symptoms.

24 MS. BENT: Thanks, Tom. I think it would be
25 really helpful if we could hear kind of about the

1 treatments that you've tried personally and your
2 personal experiences.

3 TOM: Yes, I'll do that right now.

4 MS. BENT: Thank you.

5 TOM: So the way I stumbled upon this approach
6 was I've been battling long COVID for three years, since
7 early in the pandemic. And just by chance, initially, I
8 was ravenously hungry and I gained like 15 pounds. And
9 I don't like diets. I decided to restrict my time, my
10 eating, to just eight hours per day. And I went to a
11 low sugar, no wheat flour diet and after doing that for
12 a couple of weeks, I remember the Sunday I had a major
13 flare-up of my brain fog or headache, and then suddenly
14 after that it was gone. And that was miraculous.

15 I live in Colorado. I was able to start doing
16 half-day hikes in the mountains, although initially I
17 had severe shortness of breath at altitude and I found
18 that I had severe post-exertional malaise the next day.
19 So I'd be fine for a half-day hike and then I would have
20 the PEM would hit me the next day and I'd have to nap
21 for a couple of hours.

22 I had been reading and on YouTube and
23 everywhere kind of exploring the potential of this
24 internal cellular house cleaning process called
25 autophagy. And one thing that is known to stimulate

1 this internal cellular house cleaning process are short
2 water fasts. And so I tried my very first water fast.
3 I did a three-day water fast where I didn't eat
4 anything, although I did drink salt water for
5 electrolytes. And then I rested for a couple of days
6 and amazingly, I was able to do a full-day hike in the
7 mountains. And the very next day I did a second big
8 hike in the mountains. So all of a sudden my post-
9 exertional malaise was gone. In fact, I was fortunate
10 to fully recover after four months.

11 I got COVID again. After some elk hunting and
12 backpacking. It was much more severe. And I started
13 doing these periodic short one- or two-day water fasts,
14 like once a week or once every other week. I also
15 started taking like on the weekends, I wasn't doing a
16 water fast, I would take 600 milligrams of resveratrol,
17 another putative autophagy inducer, and that's mostly
18 known from cell culture research because they can't yet
19 measure this well in living and breathing people.

20 Anyway, I had 10 or 12 typical symptoms and by
21 March I recovered to zero symptoms. Severe insomnia was
22 my last symptom to suddenly go away and I had zero
23 symptoms for a month. And then I had severe emotional
24 stress related to my mom's suddenly declining health.
25 And also I did some heavy spring snow shoveling in

1 Colorado, which was ill-advised, and a day or two later
2 I had a relapse and I had symptoms I'd never had before.
3 My stools turned white for a week. I've seen a
4 kaleidoscope of symptoms and I think a long lot of long
5 haulers do.

6 MS. BENT: Yeah.

7 TOM: And my hypothesis is that I very much
8 fall in the low level viral persistence camp. I think
9 our cells are sick, we have associated cellular
10 metabolic dysfunction and I think that wherever we have
11 the aches and pains, like our gut aches or our brain fog
12 or random kidney pains or chest pains, I think that
13 reflects sites of viral persistence. We can't prove
14 that yet, but the Chair Tau, et al. NIH study certainly
15 shows the virus is capable of infecting a wide variety
16 of cell types and organs.

17 MS. BENT: Great. Thanks so much. Thanks so
18 much, Tom. Really, really appreciate you calling in. I
19 know you were on hold for quite some time, so really
20 appreciate your patience with us as we moved through our
21 callers.

22 TOM: Yeah. No problem.

23 MS. BENT: So now I'm going to turn to Beth on
24 line seven.

25 BETH: Hi.

1 MS. BENT: Hi, Beth. Thanks so much for
2 calling in and your willingness to kind of share your
3 thoughts about some treatments and your treatment
4 experiences.

5 BETH: Thank you. Yes, and I'll be brief. I
6 know you're doing a great job sort of keeping us on
7 track and I know we all have so much to say because
8 there's not a lot of people out there listening to us.
9 So I feel everyone's frustration and I honestly just
10 want to thank everyone for how brave they are --

11 MS. BENT: Yes, absolutely.

12 BETH: -- who've called and be so transparent.
13 And I could sort of repeat most of what everyone has
14 said as far as symptoms and devastations to my life and
15 my family and everything. But I'd like to address
16 treatments because that's what we're speaking of now, or
17 I feel like more lack thereof. I honestly think that
18 the well-intended sort of mainstream approach to
19 medicine that America has, has almost, certainly not on
20 purpose, for most, I believe made it worse for many of
21 us. And I think that really needs to be heard by those
22 who have the power.

23 I have notes, so forgive me, and they really
24 are short. But because of my memory, it's difficult for
25 me to sort of stay on track. And I've tried to write

1 down my thoughts during this because literally in
2 doctor's appointments, I think what people don't realize
3 is we forget what to talk about in the doctor's
4 appointment. So when we finally have a doctor and we
5 need things addressed, we forget them. And these
6 clinics, these so-called clinics aren't set up like a
7 cancer center. They aren't set up with patient
8 advocacy. They aren't set up.

9 I liken it to sort of opening clinics that are
10 for paraplegics, but not having ramps for them to get
11 in, asking them to get up and walk over to get weighed.
12 They're ill-equipped. They're not prepared for us. And
13 three years into this and I got sick in June of 2020, to
14 me, it's sort of disgraceful, honestly, because the
15 damage that this is doing to us, the added damage, is
16 insurmountable that in getting, trying to get treatment,
17 even at the supposed best clinic. I moved up here
18 temporarily from Florida to Washington DC to get help
19 from what was a so-called clinic opening up at George
20 Washington. Everybody in that hospital is gone by their
21 own frustration.

22 So that's one issue that I think we can't
23 ignore. Many doctors who I've had sort of off the
24 record conversations with agree. Many have left the
25 clinic, quote, unquote, because of their own

1 frustrations, but I think the damage it creates in us,
2 even listening to this call, and I'm sure many of the
3 patients and long COVID people are experiencing what I'm
4 experiencing, which is just this heightened level of
5 sort of PTSD, which I struggle with a lot.

6 My main symptoms now, although there's a
7 myriad of symptoms, are severe memory loss, PTSD,
8 stuttering, bruising, POTS, huge executive function
9 issues, heart shock, insomnia, muscle atrophy. But
10 what's interesting to me is after months of expensive
11 physical and cognitive therapies, from the, quote,
12 unquote, best, from Mount Sinai to George Washington,
13 basically everyone came to the conclusion that all this
14 trial and error, which I understood and still
15 understand, that I wasn't going to make much more
16 improvement until I got a handle on my PTSD, which I
17 agree with, by the way.

18 But there's sort of this block that happens.
19 It's really difficult for us to physically and
20 cognitively heal when you're suffering from this odd
21 sort of unusual, not yourself anxiety or PTSD, for lack
22 of other diagnosis. I don't know what it's called, but
23 it's bizarre.

24 MS. BENT: And so is that what you're
25 thinking, what you're thinking, that would be the

1 symptom that you would prioritize for treatment, as it's
2 kind of the gatekeeper to maybe some of the others in
3 your case?

4 BETH: I do, I talked to a lot of people. I
5 think most of us have learned more from each other than
6 anywhere else. But one of the problems though is that,
7 and it's almost a governmental problem, so it's great
8 that we're talking to you guys, because when doctors can
9 regularly hand out opioids and narcotics, but they can't
10 hand us injections of vitamin D to take home or
11 glutathione or B12 or all of these things that a lot of
12 people have identified as help, there's something wrong
13 with that system.

14 This gentleman, Kevin, talking about spending
15 hundreds of dollars. I'm in that same boat and I can't
16 afford it. I'm going bankrupt over it. The other thing
17 that I found really interesting is so it seems like the
18 very things that are helpful to us, like, for whatever
19 reason, the government doesn't sort of get involved in,
20 which is supplements and functional medicine, Eastern
21 medicine approaches, and it's hurting us.

22 One thing I do want to ask for the doctors to
23 look at is in physical therapy, I heard people talking
24 about getting on treadmills, and here we go again, this
25 fancy word, Pilates, that seems like it's something that

1 rich housewives do was the most successful approach to
2 my getting through some of my physical therapies
3 because, think about it, you get to lay down, you can
4 strengthen your body without being upright, but yet my
5 insurance won't cover that. That's my --

6 MS. BENT: All right. So I'm just going to
7 ask you just -- I think we need to wrap it up because
8 we're running short on time, and there are others that -
9 - and some polling questions that we need to get. So if
10 you maybe want to choose one final topic.

11 BETH: Well, I think that's it. I would ask
12 you guys to look at the things that you probably don't
13 normally look at. And while you've been three years
14 looking for answers, you have a lot of people giving you
15 the same exact information. It's supplements, it's
16 physical therapies that maybe aren't the norm that need
17 to be looked at. And we need help to get them and get
18 them immediately so that we can live our lives and
19 become better. So that's what I would ask is that you
20 would look where you don't typically look and help
21 people financially get these things through the
22 mainstream as opposed to them having to be self-financed
23 by so many of us. Thank you so much.

24 MS. BENT: Thank you. So now we're going to
25 take a brief break from calls and we're going to turn

1 back to our final polling question for the session. I
2 hope everyone has their cell phones ready and we'll be
3 moving on to that question in just a moment. So for the
4 question, the question is for the medical products or
5 interventions that you use, what would you consider to
6 be the most burdensome aspect of the treatment?

7 And you can choose up to three answers. The
8 answers are, A, how the treatment is administered; B,
9 the time it takes to receive or administer the
10 treatment; C, the treatment only provides minimal
11 benefit; D, the treatment is effective only for a short
12 term; E, there are bothersome side effects of the
13 treatment; C, you have a concern about serious risks
14 from the treatment; D, there's uncertainty about the
15 long term effects of the treatment; H, there's
16 difficulty accessing the treatment; and I, anything
17 else.

18 All right. And looking at the responses, it
19 seems to be mostly split between difficulty accessing
20 treatments and the treatment can only provide minimal
21 benefit. But it seems like people are endorsing all of
22 the responses.

23 All right. So maybe now, while we're looking
24 at these results, let me turn to Shannon. Shannon, do
25 you have any comments that you want to share about

1 people's thoughts on ideal treatment and priorities?

2 MS. SPARKLIN: Yes. Thank you, Robyn. So in
3 terms of the comments we're receiving regarding ideal
4 treatments and symptoms that individuals with long COVID
5 would prioritize for treatment, many comments are saying
6 that patients would prioritize treatments that improve
7 fatigue and post-exertional malaise and brain fog.

8 One comment regarding ideal treatment stated
9 that an ideal treatment would include not just treating
10 symptoms, but treating the root cause of issues. And
11 that individual would want to look at the root cause,
12 which includes drugs for mitochondrial dysfunction, IVIG
13 for immune deficiency and autonomic dysfunction, and
14 anticoagulants and vagus nerve stimulation for autonomic
15 dysfunction and microclots. And that same individual
16 would prioritize treatment for post-exertional malaise
17 and general fatigue.

18 Another comment mentioned that a successful
19 treatment outcome would be them being able to be more
20 functional in their daily life, work full-time and get
21 back to some of the physical activities, including
22 hiking that they used to enjoy. Another comment
23 mentioned that they would like for treatments to focus
24 on microclots, viral persistence, managing symptoms
25 while work continues to identify mechanisms and causes,

1 and that managing the symptoms would be helpful to
2 include careful screening for post-exertional malaise
3 before recommending physical therapy or exercise, since
4 that can tend to exacerbate the post-exertional malaise.
5 Thank you.

6 MS. BENT: Thanks, Shannon. We only have
7 about five or six minutes before break, so we're going
8 to try and take maybe two more calls before we move into
9 the read. Our questions are going to -- we'd really
10 like the people calling in to speak a little bit about
11 what we've just been talking about, the challenges to
12 some of the treatments, as well as kind of what they
13 would look for in an ideal treatment for long COVID.

14 And so with that, let me turn to Laura on line
15 four.

16 LAURA: My problem with accessing treatment
17 was that I was gaslighted and I was having severe
18 shortness of breath, but they only gave me treatment for
19 that because I was asthmatic. If I weren't, they would
20 have just dismissed me. And I had to find my own
21 treatments. And I had a severe fatigue and post-
22 exertional malaise. I was too weak to feed myself, but
23 I had to look into research myself on chronic fatigue
24 and found that I could take CoQ10 soft gels and NAD or
25 niacin and L-carnitine. And I regained my energy by

1 leaps and bounds. And my pulmonary and other symptoms
2 mostly went away too because my body had the energy to
3 heal itself. But I had to figure that out myself. I
4 also found compelling information with fresh ginger has
5 improved my energy level even more, and I'm very
6 energetic now, and it helped with brain fog and limiting
7 sugar also helped me. But I had to be my own doctor.

8 And because of the gas lighting, there's a
9 long COVID clinic in my town, but I don't feel I can go
10 there because the doctor who gaslighted me was also
11 there. And the gaslighting just accumulates in your
12 medical file and it encourages other doctors to not take
13 your symptoms seriously, which can be a very big
14 problem, especially if you're in the EE with heart
15 attack symptoms. But if I could get treatment from a
16 doctor, I would like an antiviral. There's one not
17 available in the U.S. So I can avoid reinfection and
18 not get who knows what other symptoms that I may not be
19 able to treat myself. Okay.

20 MS. BENT: Yes. Thank you very much.

21 LAURA: Okay.

22 MS. BENT: All right. Let me turn to Adina on
23 line ten as our final caller to just share a little bit
24 of experience before we read out to break. And Adina, I
25 apologize, but we only have a few minutes before the

1 break.

2 ADINA: I will keep it brief.

3 MS. BENT: Thank you.

4 ADINA: Thank you for taking my call. Thank
5 you to the FDA for focusing on patient-focused drug
6 development for long COVID. Prior to COVID, I was a
7 healthy 40-year-old who was working three separate part-
8 time jobs in the modern gig economy. I've lived in New
9 York City for 20 years, and I do not drive, so I've
10 always walked a lot. As a gig economy worker, I was
11 used to walking one to two miles regularly to save
12 money.

13 I've had long COVID since I was first infected
14 in March 2020. My symptoms have included profound
15 fatigue that makes it impossible to shower or even brush
16 my teeth sometimes, PEM, which is post-exertional
17 malaise, joint pain and swelling, limb pain,
18 inappropriate sinus tachycardia, palpitations,
19 lightheadedness, orthostatic intolerance, brain fog,
20 numbness and burning pain in my left leg, dry eye and
21 intermittent tinnitus, ear pain, throat pain and nausea.

22 The symptoms are worse if I do too much.
23 Doing too much can make all of my symptoms worse. Too
24 much can mean too many hours of sedentary, office-based
25 work. It can mean showering and then getting dressed.

1 It can mean vacuuming the floor. I've been treated at
2 the Mount Sinai Post-COVID Care Center since August
3 2020. I was referred to pulmonology, cardiology,
4 physiatry, neuropsychology and more. Each of these
5 specialties has treated me separately in turn and looked
6 for anything diagnosable that can be pinned to an
7 existing test.

8 The cardiologist diagnosed me with post-viral
9 fatigue syndrome, post-viral dysautonomia and severe
10 obstructive sleep apnea, as well as familial
11 hypercholesterolemia, put me on statins and eventually
12 beta blockers to address my inappropriate sinus
13 tachycardia. The pulmonologist found a blood clot in my
14 right lung in December 2020 and put me on an
15 anticoagulant, which helped me with a sharp stabbing
16 chest pain as well as with calf cramps and an inability
17 to walk.

18 Cognitive neuropsychology said that I did not
19 have brain damage but I had some issues, including poor
20 fine motor control and variable processing speed, as
21 well as poor phonemic fluency. As someone who used to
22 copy edit complicated legalistic documents in multiple
23 languages, I could have told them that I was having
24 issues with phonemic fluency.

25 I was further referred to hematology and

1 rheumatology. Rheumatology identified some abnormal
2 autoantibodies but no diagnosable autoimmune condition.
3 She recommended that I stay on top of monitoring some of
4 these abnormal autoantibodies. Physiatry recommended
5 electrolytes and maximum compression, high-waisted
6 runner leggings.

7 Finally, I've been seeing an ME/CFS specialist
8 since April 2020, when I was diagnosed with ME/CFS. She
9 put me on a number of supplements that are meant to
10 address mitochondrial dysfunction and eventually also
11 low-dose naltrexone, which is an off label use. I don't
12 know if any of the supplements are helping, but the low-
13 dose Naltrexone helps with my joint and limb pain.

14 I did physical therapy first at Mount Sinai
15 and then through the Pulmonary Wellness Foundation here
16 in New York City. I think that the pulmonary wellness
17 that included supplemental oxygen, both while I walked
18 slowly on a treadmill and while I rested afterwards,
19 helped me while I was doing it, but the effect
20 disappeared once I stopped their protocol after a few
21 months.

22 I have found some things for online patient
23 support groups that have helped, including curcumin with
24 black pepper extracts that seems to help my joint pain
25 and swelling. Over time, with all the specialties I've

1 seen and everything I've tried, I've seen the most
2 improvement by resting, pacing and convalescing.
3 Staying within my energy envelope does the most for
4 keeping my symptoms tolerable.

5 The symptoms I would absolutely prioritize for
6 treatment in my case are fatigue and myalgia. I
7 desperately wish that I could walk miles without
8 consequence again. I desperately wish that I could work
9 a full-time job again. I've managed to increase my work
10 from two to five hours a week during my first two years
11 of long COVID to about 10 hours a week now. But I can't
12 do 10 hours a week during weeks when I also do too many
13 things such as any cleaning or socializing.

14 An earlier caller said that the interventions
15 they've tried so far have been to treat, Band-Aid,
16 suppress, help or cope. It's a very good line. I agree
17 with that. I think that drug development has to focus
18 on root underlying causes and addressing them rather
19 than suppressing symptoms without addressing whatever is
20 causing them. In addition, more treatments have to take
21 a person's whole body into account. It's very hard when
22 everything is subdivided into specialties and
23 subspecialties.

24 Challenges to treatment are that they are
25 expensive, not covered by insurance, such as supplements

1 and low-dose naltrexone, which is not FDA approved for
2 ME/CFS and so it's prescribed off label and that they
3 don't work that well or they don't suppress all of the
4 symptoms. Finally --

5 MS. BENT: And Tina, I'm sorry. we're running
6 a little bit over. So if you could limit it to maybe
7 just one more comment. Thank you.

8 TINA: My last point is that I know the FDA --
9 I know federal government agencies oversee supplements
10 in the U.S. But someone should (indiscernible) to know
11 what you're buying what the bottle is saying is inside.
12 So many people are trying so many supplements to treat
13 long COVID, and it really needs to be overseen by
14 someone from the government. That's it. Thank you so
15 much for your time.

16 MS. BENT: Thank you so much. Really, really
17 appreciate and apologies that we have to move on to
18 break now. So for now, we're going to move to a 10-
19 minute break. We'll reconvene in 10 minutes, which I
20 believe will be about 2:32 Eastern time, and at that
21 time, we'll move on to topic three for the day, clinical
22 trials. Thank you all, and we'll see you in just 10
23 minutes.

24 (Recess)

25 TOPIC 3: CLINICAL TRIALS

1 MS. BENT: Welcome back, everyone. I hope you
2 had a good, albeit brief, break. In keeping with our
3 theme for the day, we have limited time, so we're going
4 to move straight into topic three. As we mentioned,
5 topic three will focus on your thoughts around clinical
6 trial participation. This includes sharing what you
7 think about when considering whether or not to
8 participate in clinical trials, what outcomes of trials
9 for long COVID do you think are the most important
10 things to measure and what experiences have made it
11 easier or harder for you to participate in the clinical
12 trial.

13 We have five panelists who will start off our
14 discussion by sharing their thoughts and experiences.
15 Before we launch into our patient experiences, I do want
16 to let you know that our first question for the open
17 discussion session is if you considered participating or
18 have participated in a clinical trial for long COVID,
19 can you please tell us about your experiences. And so
20 with that, we're about 30 minutes away from people
21 sharing their answers.

22 So now let me turn to our panelists and ask
23 them to share some of their experiences with us. We're
24 going to start off with Michelle. Michelle, would you
25 please share some of your experiences with clinical

1 trials and some of the things that you considered?

2 MICHELLE W.: Yes. I am a parent of four
3 children, two of whom have long COVID. My daughter was
4 16 and a half when she got COVID in July of 2020. Her
5 life has been totally changed since that infection. She
6 was an honors student who was going to graduate high
7 school at least a year early with a goal of becoming a
8 doctor, but instead she is unable to start college. She
9 has had multiple hospitalizations, abdominal surgery,
10 used a feeding tube for 18 months, collected many
11 diagnoses and now takes many, many medications that cost
12 our insurance tens of thousands of dollars each month.

13 We used the study that was published by Mount
14 Sinai about autonomic reconditioning therapy to guide
15 her physical therapy treatments both in a clinic as well
16 as incorporating physical therapy using equine movement
17 to treat the physical fatigue and the worst of the
18 physical symptoms. Currently, her most debilitating
19 symptoms are significant cognitive changes, language
20 issues, cognitive fatigue and daily headaches.

21 Professionally, I'm a physical therapist. As
22 a healthcare practitioner, I am very aware of the need
23 for research and clinical trials to determine underlying
24 causes of disease and treatments for them. When I saw
25 the NIH was funding a large study to determine the

1 pathophysiology and treatments for long COVID, I knew my
2 daughter and I needed to participate. The RECOVER trial
3 has made it easy for us to participate. We are lucky to
4 have a site only 20 minutes away from our home. Because
5 I manage my children's healthcare needs, I now only work
6 two days per week. Study visits are able to be
7 scheduled on my days off. There are surveys that we
8 complete at home. Staff at the study site have been
9 easy to reach via email or phone. Results from standard
10 lab tests are forwarded to us so we can submit them to
11 our doctors to avoid duplicate testing.

12 Due to the timing of when my daughter was
13 tested for COVID, she did not test positive. However,
14 she had known exposure, lost her sense of taste and
15 smell and is now clinically diagnosed with long COVID.
16 The lack of a positive test did not interfere with her
17 ability to participate in the RECOVER study, which is
18 very important, especially for patients who were
19 infected early on in the pandemic.

20 Currently, of the studies for long COVID that
21 are listed on clinicaltrials.gov, very few do not
22 require a positive PCR test. Therefore, she is not
23 eligible to participate in the majority of studies. We
24 recently chose to not participate in a study for one
25 diagnosis that she has because it required stopping a

1 very effective medication that took many months to find
2 the correct dose for her. And she did start to
3 participate in a different study of a computer-based
4 cognitive rehab program. But unfortunately, she had to
5 stop due to a significant increase in her symptoms due
6 to the cognitive exertion required.

7 When we assess participating in a study, we
8 look at does this study address one of her key
9 impairments? What are the eligibility criteria? Will
10 there be an opportunity for the control group to receive
11 the study intervention? What are possible side effects
12 of study interventions? Do treatment current
13 medications need to be stopped? How many study visits
14 are required? Is there a location close to where we
15 live? Can study visits or activities be done virtually?
16 Is there compensation for participating and are the
17 risks of the treatment worth it?

18 Whether the treatment is a rehab protocol,
19 medication, supplement or something else, our most
20 meaningful outcome at this point would be finding a
21 treatment for the cognitive dysfunction and cognitive
22 fatigue that is preventing her from returning to her
23 baseline function and from being able to go to school
24 and move forward with her life.

25 MS. BENT: Thank you, Michelle. That was

1 really, really informative, and I think we'll probably
2 want to kind of ask maybe some clarifying questions in a
3 little bit.

4 Let me now turn to Ezra. Ezra, would you mind
5 telling us a little bit about your experience as well as
6 your thoughts when considering clinical trials?

7 MR. SPIER: Absolutely. Thank you so much.
8 Hi, everybody. My name is Ezra. I live in Oakland,
9 California, and I've had long COVID for seven months
10 now. As a participant in a clinical trial, to me, it
11 all really comes down to three things: impact,
12 practicality and compassion. So I want to talk about
13 each of those as relates to the study I'm currently in,
14 which is a double blind trial of Paxlovid for treating
15 long COVID.

16 So first, impact. Impact can be broad and it
17 can be narrow. For me to be excited about a trial, it
18 needs to have broad impact. I want to test a compelling
19 and impactful hypothesis. In my case, it was a no
20 brainer. Paxlovid is a great way to test the viral
21 persistence theory, so there we go for big impact. But
22 studies also have potential impacts on me, and those
23 could be positive or negative. On the positive side,
24 here is my chance to potentially get a drug that might
25 actually help. Amazing. Again, no brainer. Even

1 better, the study lent me a smartwatch and a blood
2 pressure cuff for a sub-study. So not only am I
3 providing more data about my own body and my activity,
4 I'm actually using that data to help me and my doctors
5 manage my own health. So that's a huge benefit as well.

6 But there could be negative impacts from a
7 trial as well. Luckily, Paxlovid is relatively well-
8 known. We know a lot about its side effects and
9 effectiveness for acute disease. So I wasn't super
10 worried about negative impacts on my health. But as a
11 quick counterpoint, I also looked into a cardiac
12 rehabilitation trial. But there's no way I would
13 participate in that because it would have required
14 significant physical activity. That's the one thing my
15 doctor told me I should absolutely not be doing right
16 now. So it's really important that studies are informed
17 by clinical best practices as well.

18 Okay. Next, let's talk practicality. And I
19 think Michelle hit on a lot of these topics really well.
20 The thing that's most important to remember from my
21 perspective is that most of us with long COVID are
22 operating at just a fraction of the energy capacity of
23 the patient you might be used to. That means we need
24 you to respect our time and focus on and track the
25 things that matter most to us. And I found that the

1 study has been pretty respectful of my time. Five
2 visits in three and a half months, and they are even in
3 the process of adapting their protocol to allow for more
4 virtual visits. So that's a huge plus for many of us.
5 I also appreciate that they're tracking many of the
6 outcomes that are important to me fatigue, cognitive
7 symptoms, and impact of long COVID on my daily life. I
8 wish there was more about post-exertional malaise, but
9 I'll take what I can get.

10 Finally, let me talk about compassion. You've
11 heard a lot of stories today about some of the just
12 dreadful experiences that we're having in the healthcare
13 system. And so honestly, one of the things I've
14 appreciated most about the study I'm in is that
15 everybody I've interacted with has been caring and has
16 validated my experience. There's no gaslighting. And
17 even when I might be more knowledgeable about a topic
18 than other folks, there's appreciation and curiosity and
19 validation. It feels more like an actual collaboration
20 where we're invested in each other's health and success,
21 and that feels really good.

22 The thing about compassion is you can't fake
23 it, whether it's in your recruitment materials, email or
24 phone interactions or even seriously on
25 clinicaltrials.gov. We are very good at reading between

1 the lines and honestly, we want to work with the folks
2 who really care about us. Compassion is a balm that
3 gives me hope and makes me confident that we will find
4 answers. It costs you nothing, but it means everything.

5 So to wrap up, I just want to say we're really
6 eager to collaborate with researchers. We need you as
7 much as you need us. So let's be impactful, practical
8 and collaborate together with compassion. Thank you.

9 MS. BENT: Thank you, Ezra. I definitely feel
10 like there's some commonalities so far between what you
11 were saying and what Michelle was saying, and I think
12 that you're making some really important points.

13 And so now I'm going to turn to Liza. Liza,
14 if you wouldn't mind going ahead and kind of sharing
15 your thoughts with us, we would really very much
16 appreciate it.

17 MS. FISHER: Hi. Yes. Thank you to the FDA
18 for hosting this panel, for all of the clinicians,
19 researchers and healthcare providers that are taking on
20 this subject matter and cause, and especially to all
21 those dealing with long COVID or some other post-
22 infectious illness living at home, using those precious
23 spoons, trying to find information here.

24 My name is Eliza Fisher and a little bit of
25 background about me. I'm 38. I'm from Houston. I did

1 get COVID in 2020, and prior to that, I was a very
2 active lifestyle, international flight attendant, part-
3 time yoga instructor. I was independent living, and I
4 got COVID. I struggled to find healthcare. I ended up
5 in the ICU five weeks later and a rehab hospital for
6 three months after.

7 MS. BENT: And if you wouldn't mind just
8 slowing just a little bit down so that interpreters can
9 get things, I appreciate it. Thanks.

10 MS. FISHER: Yes, sorry. Along that time, I
11 had the gambit of symptoms that we've all heard and that
12 led me down the path of treatment and diagnoses similar
13 to the experiences that you previously heard today.
14 Additionally, I've also experienced the transition from
15 different socioeconomic status in the world and dealing
16 with different types of disability, private and SSDI,
17 Medicare and transitioning from independent living to
18 dependent living.

19 As far as my perspective on clinical trials,
20 one of the things that is unique about my case is I did
21 have a positive PCR test and a lot of medical
22 documentation in the beginning. So personally that
23 hasn't kept me out of a lot of trials, but it is
24 something that is very common in the community. I also
25 had a caregiver that was able to help me with

1 transportation and reminders to fill out paperwork and
2 helping me not only in preparation for the different
3 appointments, but in the different appointments as well.

4 Things that have made clinical trials more
5 difficult. I think in general, anything around
6 accessibility and privilege and mean and root cause is a
7 lot of just financial access and accessibility.
8 Anything that is in-person is extensively more difficult
9 than anything that can be telehealth or done online and
10 it also continues to add to the cost associated with
11 participating in trials, as you've already experienced a
12 loss of either employment and income or healthcare
13 coverage.

14 An example I would be -- an example I had was
15 in 2021 a Houston company tried to start a stem cell
16 trial and when I called in to see if I was able to
17 participate in it, I was told that you must biobank your
18 stem cells. They offered different packages ranging
19 from \$3,000 to \$10,000. After the biobank was made,
20 then I could participate. However, being I was working
21 on disability, this cuts trials like this out and a
22 significant population affected by these medical
23 conditions just can't participate in a trial like this.

24 Another experience, I tried to get in a
25 clinical trial with CytoDyn for leronlimab out to Texas

1 because it was only having certain locations. We found
2 a trial site, researcher and everything to connect and
3 had a diverse population here. However, that wasn't
4 able to be successful for still reasons I don't entirely
5 know.

6 Different things that have made trial
7 participation difficult, also off label treatments that
8 I may currently be on, like steroids, may mean that you
9 don't meet exclusion criteria. And there's other
10 problematic exclusion criteria in clinical trials that
11 involves the activity ranges for vitals. They're just
12 not sensitive for this nuance of patient population.

13 Then any side effects weighing into my
14 decision. To be perfectly honest, in my personal case,
15 every time I read a list of side effects I thought, oh,
16 that's my Saturday. So I think that there's a lot of
17 people who are just willing to try anything like myself,
18 and the side effects aren't necessarily as prohibitive.
19 But when you go into a patient community and you find
20 other people who have been trying it, you see something
21 that could possibly trigger an increase, it may cause
22 you to refrain. But I think adjusting these
23 interventions with like micro dosing and slow titration
24 schedules may be able to allow people to access these
25 more.

1 Other considerations, root source being
2 financial and physical support. There was a section on
3 regarding a placebo. If a placebo was offered in a
4 trial and the trial did prove that the treatment was
5 positively advantageous, I would consider doing the
6 trial and risking a placebo if I knew that the
7 advantageous results would be provided after the trial.

8 And overall outcomes that are most important
9 to measure in trial settings are energy level,
10 particularly dealing with post-exertional malaise,
11 fatigue, brain fog, neurocognitive function, pain,
12 spasticity, any and all related symptoms to autonomic
13 dysfunction and performance of daily life activities.

14 MS. BENT: Thank you so much, Liza. I really,
15 really, really appreciate that. So now we're going to
16 turn to Ryan to have Ryan. Hi, Ryan.

17 RYAN: Hello. Thank you for having me.

18 MS. BENT: Thanks. Please go ahead.

19 RYAN: So I'm Ryan. I have had long COVID for
20 about a year and a half. My primary symptoms have been
21 brain fog, post-exertional malaise, sleep issues, heat
22 intolerance, tinnitus and epilepsy. And so I think one
23 of the most important aspects of any sort of clinical
24 trial is making sure to measure biomarkers properly and
25 to make sure that they are properly controlled because

1 my symptoms have improved sort of moderately over time.
2 So sometimes I'll see like a study that's been trialing
3 a medication for six months and they've seen moderate
4 improvement, but that's my experience without
5 medication.

6 So I think controls are one of the most
7 important parts of clinical trials and I think measuring
8 biomarkers is also really important because I know that
9 there are sort of these observational trials happening
10 right now, but we also need medications right now. And
11 having a clinical trial that measures biomarkers while
12 providing medication, you can see that if the symptoms
13 improve, also if the biomarkers change at all,
14 especially since COVID probably has -- it's a complex
15 multisystemic disorder. It probably has multiple
16 causes. So you could even focus in on if a medication
17 only helps, say, 30 percent of people who take it, which
18 30 percent, which biomarkers are associated with that,
19 which biomarkers change on the medication.

20 And then also it might be important because if
21 some biomarkers improve but some symptoms don't, again,
22 COVID is a probably multisystem disorder, so something
23 that doesn't provide a lot of help on its own might be
24 like a critical part of a larger therapy treating
25 multiple issues at once.

1 But that said, I do think it's also critically
2 important to measure subjective outcomes as well on
3 post-exertional malaise, brain fog. These are some of
4 like the most debilitating symptoms that we're all
5 having and there's no good biomarker proxy for them yet.
6 So it's very important to include that in any sort of
7 study on how effective medications are.

8 Sort of biomarkers I would be looking for
9 would be sort of vascular ones involving things like
10 microclotting or endothelial dysfunction, immunological
11 biomarkers like T cell disturbances or cytokines that
12 are associated with perhaps chronic infection or just
13 immune dysfunction in general as well as neurological
14 markers like imaging tests or neuroinflammatory markers,
15 indicators of blood-brain barrier dysfunction, things
16 like that, as well as metabolic markers like disruptions
17 to lipid metabolism, oxidative stress, increases in
18 anaerobic respiration.

19 And I do think it's also important to try
20 testing multiple medications at once in the same trial,
21 because, again, this is probably a complicated
22 multisystem disorder. So it would probably be useful to
23 have something where, say, if you have two medications,
24 like immune dysfunction might be causing some of the
25 vascular issues, and the vascular issues might sort of

1 prevent the immune system from sort of pulling itself
2 together and clearing out the rest of the virus. So you
3 might need something to treat both of them at the same
4 time. So seeing studies that would, for example, have a
5 control group, a group receiving something for vascular
6 issues and a placebo, a group that's taking an antiviral
7 and a placebo and a group that's taking both at the same
8 time, seeing how sort of these different medications, if
9 they have any sort of synergistic effect.

10 In terms of what I look for specifically when
11 I'm looking for a study, due to my brain fog issues, I
12 do not feel comfortable driving. So I really have to go
13 to an area that is accessible by public transport. I'm
14 in the RECOVER program or the RECOVER study at Mount
15 Sinai. And being able to take public transport into New
16 York City has helped a lot. I also receive
17 reimbursement for public transport costs, which also
18 helps because I have not been able to work. And another
19 part of the study that I like is that you do get your
20 results back, which is also useful just for my own
21 personal medical -- I can provide it to medical
22 providers and make further treatment options based on
23 that.

24 But I think sort of Liza touched on this a
25 little bit, like I can't work or really even live like a

1 normal life. So I'm at a point where I would be willing
2 to try really a lot of clinical trials simply because
3 there's a level of sort of desperation and this idea
4 that we need sort of treatments as soon as possible.
5 We've all been trying to do our research and everything,
6 but that's not really, I think, a sustainable option in
7 the long run. So, yeah, I would like to see more of
8 these trials going forward.

9 MS. BENT: Great. Thank you. Thank you,
10 Ryan, and really appreciate that. And I continually
11 forget to mention that again, that this meeting is being
12 recorded and will be posted on the FDA website. So for
13 those of you who may not be able to stay through the
14 duration of a six-hour meeting, which we know is
15 exhausting, please know that the meeting will be
16 recorded and will be available. It will just take us a
17 few days to get everything up and running.

18 But with that, let me turn over to Lisa.
19 Lisa, to share your thoughts on this. I know you have a
20 lot and you've thought a lot about this, so I really
21 appreciate you joining us. Please go ahead.

22 MS. MCCORKELL: Thank you, Robyn. Hi,
23 everyone. My name is Lisa McCorkell, and I've had long
24 COVID since March of 2020, and I'm one of the co-
25 founders of the Patient-led Research Collaborative, who

1 are a group of people with long COVID who conduct
2 research on long COVID. I am one of many millions of
3 people with long COVID, and our numbers continue to grow
4 as COVID spreads. While I am generally a mild case of
5 long COVID, my symptoms impact my everyday life, having
6 developed postural orthostatic tachycardia syndrome,
7 post-exertional malaise, cognitive dysfunction, fatigue
8 and premenstrual dysphoric disorder.

9 As I've tried to participate in clinical
10 trials thus far, I've run into a few barriers. First,
11 there's just not enough happening right now,
12 particularly given the scale and severity of long COVID.
13 Second, despite being heavily involved in long COVID
14 research myself, it takes significant effort to even
15 find clinical trials. Researchers need to better
16 promote their studies to the patient population and not
17 focus solely on recruiting through long COVID clinics,
18 which have many barriers to entry. And third, because I
19 got COVID so early and was not able to be tested, I'm
20 unable to participate in any clinical trials that
21 require a positive COVID test for inclusion.

22 And as Michelle said earlier, it won't just be
23 me who is excluded. A minority of COVID cases have
24 actually been properly documented by PCR due to
25 inaccessibility and also PCR tests having high false

1 negative rates, particularly among women and people
2 under 40 years old. And antibody tests are also not
3 reliable, as women and people with mild infections are
4 more likely to not seroconvert and serorevert. It's
5 critical for clinical trials to, at minimum, have an arm
6 that allows for clinical diagnoses of COVID so that the
7 millions of people like me can participate.

8 If I am eligible and can find clinical trials
9 though, there are a few things I would consider before
10 signing up. First, the intervention. As someone who
11 has post-exertional malaise, I would not participate in
12 a clinical trial that is testing graded exercise
13 therapy, as my own baseline has decreased due to
14 exercise, and research shows that this harms people with
15 post-exertional malaise.

16 I would prioritize participating in clinical
17 trials that are testing interventions that have a base
18 and existing evidence on long COVID and other infection
19 onset illnesses, and ones that are of importance to the
20 patient community. These include antivirals,
21 antihistamines, anticoagulants, JAK/STAT inhibitors and
22 immunomodulators. I would also consider the side
23 effects of the intervention, particularly if there is a
24 high likelihood my symptoms could be permanently made
25 worse on the intervention. But I would be willing to

1 risk some side effects for drugs that are showing
2 promise from patient anecdotes and that test a promising
3 hypothesis.

4 Due to limited energy as well as risk of
5 getting reinfected with COVID, I would be more likely to
6 participate in a decentralized clinical trial that is
7 fully remote or requires only a few clinic visits. But
8 if the evidence behind the drug is strong and of
9 priority to the patient community, I would consider more
10 in-person clinic visits with additional travel that is
11 reimbursed. However, it's important that trials also
12 give the option to have at-home visits to ensure
13 (indiscernible) COVID patients can participate.

14 I would consider the clinical trial design,
15 whether patients are stratified by phenotype and whether
16 the design is considering and measuring differences
17 based on illness duration, where patients are in their
18 menstrual cycle, any mast cell reactions, post-
19 exertional malaise from clinic visits or the
20 intervention itself and any potential impact of or to
21 endothelial dysfunction and organ damage.

22 I would prefer to participate in a crossover
23 trial where everyone receives an intervention. But I
24 would also personally be okay with the risk of receiving
25 a placebo as long as I can continue taking other

1 medications and supplements that currently help me
2 somewhat manage my symptoms.

3 In terms of outcomes to prioritize, I would
4 want a trial to ensure clinical significance that the
5 intervention has a meaningful impact on my life. Ways
6 to measure this include quality of life measures,
7 standardized tools for symptoms and conditions like the
8 DSQ-PEM and COMPASS-31 and the severity of our most
9 impactful symptoms. And while it is often argued that
10 there are no specific biomarkers for long COVID yet,
11 there are tests that often come back abnormal in people
12 with long COVID and are often pulled from research into
13 overlapping conditions and comorbidities like ME/CFS and
14 dysautonomia. Examples of these include cerebral blood
15 flow, natural killer cell function, T cell functioning,
16 microclots and levels of reactivated virus.

17 Overall, there are millions of patients who
18 desperately need well-designed, accessible trials
19 testing therapeutics that are a priority to the patient
20 community. Excuses of no definitive biomarker or murky
21 endpoints are not acceptable. There are ways to do this
22 well, and we need to do it now. Thank you.

23 MS. BENT: Thank you, Lisa. And so I want to
24 just take a moment to thank all of our panelists for
25 really sharing their thoughts and sharing their stories.

1 So thank you to Michelle and Ezra, Liza, Ryan and Lisa.
2 And I think that we may have some follow-up questions
3 from my FDA and HHS colleagues. So I hope that the
4 panelists -- I think I gave you a heads-up that we might
5 have some clarifying questions or some follow-up
6 questions. So I hope you'll be willing to consider
7 answering some of these questions.

8 So with that, let me turn to Dr. Habal, one of
9 my colleagues, to ask maybe the first question for
10 panelists. And if you're willing to answer, please
11 either just, like, raise your hand or turn on your
12 camera or whatever it is that signals to me that you're
13 willing to answer. Thank you.

14 DR. HABAL: Good afternoon. I wanted to thank
15 you all for sharing your experiences today. And I have
16 a two-part question. I heard several panelists mention
17 that brain fog is a common symptom that you are
18 experiencing. So for the first part of my question is,
19 how do you measure brain fog in your words and
20 experiences? And the second part is, what would you all
21 consider is a meaningful improvement either in this or
22 in any of the symptoms that you had experienced? And
23 thank you again for your insight.

24 MS. BENT: Great. Thank you. All right. So
25 we'll start with Michelle, and then we'll go to Ryan.

1 Michelle, go ahead, please.

2 MICHELLE W.: Hi. So one of the ways we
3 measure brain fog in our house is I have a regular
4 activity that I do with my daughter. I give her 10
5 letters and then I give her five minutes, and I ask her
6 to come up with as many words as she can in those five
7 minutes. And so it's looking at her cognitive function,
8 her language abilities and we've done it enough times
9 that I will repeat them so I can see it's not just the
10 letters that I gave her. So that's one of the ways.

11 We also have kept track, one of the biggest
12 things that happens for her is that she does what they
13 call paraphasia, which is where she might want to tell
14 me to close the door one day, and instead she said, can
15 you please close the bananas. So she uses the wrong
16 words for things, and so we keep a running list of those
17 to have an idea of is it happening more frequently, is
18 it happening less frequently, are the words becoming
19 similar to the words that she actually meant. Bananas
20 and doors have nothing to do with each other, but
21 bananas and oranges would be a positive sign for us.
22 Those are some quick and easy tests that we do at home
23 just to keep an eye on what's going on with her.

24 MS. BENT: Great. Thank you. And do you have
25 an idea, Michelle, before I move on to Ryan, do you have

1 an idea of what would be a meaningful improvement as far
2 as --

3 MICHELLE W.: Yes.

4 MS. BENT: If you couldn't make it completely
5 resolved, what would meaningfully better look like?

6 MICHELLE W.: Her original life goals were to
7 become a doctor. She is aware at this point that
8 without significant recovery, that may not be a
9 possibility anymore. She has documented significant
10 cognitive decline and change from her baseline status.
11 And so if that's no longer a possibility, at a minimum,
12 we are looking for her to be able to return to school.
13 She can't be in school right now. A half hour of
14 cognitive exercise, and she's spending hours recovering
15 from it. So being able to tolerate returning to school
16 would be the most meaningful improvement for us.

17 MS. BENT: Thank you. Thank you. Let me now
18 turn to Ryan.

19 RYAN: So for me, this sort of goes back into
20 why I was saying that subjective biomarkers are also
21 really important to measure because I don't know of,
22 like, a good test specifically because my brain fog also
23 ties into my post-exertional malaise. So I know that I
24 am at least somewhat capable of putting it together
25 more, like I'm doing sort of right now and that might

1 show a more normal test result or something, but I'm
2 going to pay for it a lot more later. Like this
3 evening, I'll probably just have to sort of lay down and
4 not do too much, possibly even tomorrow as well. So for
5 me, I think it would be very difficult because I don't
6 know the best type of objective test to sort of run. I
7 do know that when I do have brain fog, sometimes I can
8 have trouble with reading comprehension. I tend to sort
9 of pause more during speaking and things like that.

10 But yeah, like I said, unfortunately, it is
11 very sort of subjective and I can especially sort of
12 force myself to be more cognitively present if I have to
13 be. In terms of what improvement looks like, I actually
14 started taking guanfacine as a medication because I saw
15 a case study that seemed to improve brain fog and that
16 actually has improved my symptoms. I noticed that sort
17 of when I do exert myself mentally, I'm able to do it
18 for a longer period of time. And when I do crash, I
19 tend to recover quicker.

20 So I do know that there is improvement
21 possible because I have experienced it, but it is very
22 difficult to sort of, I think, measure and also to sort
23 of just even put into words. So I think that just
24 having subjective measures of brain fog might be and
25 whether it improves or not might be an important aspect

1 of treatment in clinical trials.

2 MS. BENT: Thank you. Let me turn to Ezra.

3 MR. SPIER: Hey. Thanks so much. Really good
4 questions. In terms of measuring brain fog, I want to
5 be a little bit blunt. I'm looking to you, the
6 clinicians, to tell me how to manage this. I'm happy to
7 share this. I appreciate you asking the question, but
8 we are literally in a reduced cognitive state, so it's
9 really difficult to even answer these questions, let
10 alone give you some specifics.

11 That being said, I think what I've experienced
12 is -- the two questions you asked are actually very,
13 very similar. One really great way to evaluate brain
14 fog and post-exertional malaise is about what we're able
15 to do in our daily lives.

16 So I think about potential metrics like how
17 much time can you spend standing during a day without a
18 crash? How many hours of activity are you able to do?
19 Are you able to sustain a one-hour phone call or a one-
20 hour conversation without getting a headache? Really
21 direct, concrete things, measuring kind of our ability
22 to have daily activities I think would be highly
23 impactful. And those are the same things that are
24 meaningful.

25 I would love to be able to sit through a six-

1 hour Zoom without having a crash tomorrow. I would love
2 being able to go to a study, meaning without having to
3 explain post-exertional malaise to a study coordinator.
4 So I think that really basic day-to-day activities and
5 what we're able to do is a fantastic way both to measure
6 progress and, in turn, show progress.

7 MS. BENT: Great. Thank you. And let me turn
8 to Lisa.

9 MS. MCCORKELL: Thank you. I'll just add a
10 quick couple of things. Just in terms of objective
11 testing, the Cogstate is a really strong cognitive
12 assessment. The CNS Vital Signs, the CANTAB. So those
13 are ones that we generally recommend for cognitive
14 function.

15 MS. BENT: And do you feel that those measure
16 things that matter to patients? The way that the
17 questions are formed, they're measuring things that are
18 important to patients? Because I think one of the
19 things that we're really trying to get to, we know there
20 are a lot of measures. Some measures kind of measure
21 things that matter to patients, and some measures maybe
22 not so much. So I think that that's kind of maybe -- I
23 don't want to speak for Dr. Habal, but I think that
24 that's kind of where we are going to as far as like --

25 DR. HABAL: Yes, I agree with you completely.

1 MS. MCCORKELL: Yeah. I think importantly,
2 anything needs to test processing speed, which many
3 objective tests aren't testing processing speeds.
4 That's one of the most important things. And then in
5 terms of a meaningful difference or improvement, that's
6 why I think it's important to pair any of that with
7 quality of life measures so that you can also get that
8 viewpoint. So did it meaningfully improve for the
9 patient, and is it improving their life and how they're
10 going about living their life if they're able to work,
11 do activities of daily living, that type of thing.

12 MS. BENT: Great. Thank you. And let me go
13 quickly to Liza. And then I think we have one more
14 question from one of my other colleagues. So, Liza, go
15 ahead, please.

16 MS. FISHER: Thank you. I just wanted to
17 reiterate a little bit of what Lisa said also. Those
18 quality of life outcome measures are definitely
19 important. I myself have been able to measure some of
20 my brain fog and cognitive impairment because I got
21 neurocognitive therapy and speech therapy. So I had a
22 battery of assessments, neurocognitive assessments done
23 several times throughout the last three years. One of
24 those things when you said you want to figure out which
25 ones are good, I would like to point out that the Beck's

1 Anxiety Index specifically has three questions that are
2 skewed for those with dysautonomia. That's a really
3 poor measure to use on this population. Thank you.

4 MS. BENT: Thank you. So, Dr. Habal, did that
5 answer your question? Did you have any follow-up for
6 that?

7 DR. HABAL: No. I just wanted to thank the
8 panelists for their insight.

9 MS. BENT: Great. Thank you so much. So let
10 me maybe turn to Dr. Karimi-Shah. Did you have
11 questions for our panelists?

12 DR. KARIMI-SHAH: Thanks, Robyn. Can you hear
13 me?

14 MS. BENT: Yes.

15 DR. KARIMI-SHAH: Again, thank you to all the
16 panelists. I've been struck by all of your stories
17 today, and I think you've described how helpful this is
18 for you to be able to sort of come into this forum and
19 recount what your disease process has been like and it's
20 very helpful to us on the FDA side to be able to hear it
21 as well.

22 I'd like to come at my question from sort of
23 the other side of where Dr. Habal approached in terms of
24 a clinically meaningful benefit. From what I've heard
25 from all of you today, there are a number of disabling

1 symptoms that you all experience, and these are striking
2 to me. And I'm wondering, when we -- we obviously at
3 FDA have input into clinical trial design and which
4 drugs get used. We don't design the trials de novo.
5 And so we're always trying to assess sort of the
6 risk/benefit of a clinical trial to the patient. So I
7 wanted to approach my question from the side of risk and
8 ask what kind of toxicities would you be willing to
9 tolerate and what would you not be willing to tolerate?
10 Because this is something that we take into account when
11 we look at clinical trial design.

12 MS. BENT: All right. We'll start with Liza.

13 MS. FISHER: Hi. Could you actually repeat
14 that again? Toxicities?

15 DR. KARIMI-SHAH: Toxicities of
16 investigational therapies, like in a clinical trial.
17 Like what types of side effects or toxicities of a
18 medication, if you were entering into a clinical trial,
19 potential toxicities would you be willing to tolerate in
20 terms of things that might be beneficial for your
21 symptoms and what would just be outside the scope of
22 what you would be willing to tolerate? Is that clear?

23 MS. BENT: So for example, if a medicine was
24 going to cause you to have increased liver functions or
25 a lot of nausea or a lot of pain or, I'm just making

1 things up, but just low blood counts that would increase
2 your potential risk for infection, anything like that, I
3 think, is where you're going. Did I capture that a
4 little bit, Dr. Karimi-Shah, or was that not what you
5 were thinking?

6 DR. KARIMI-SHAH: Yeah, and I'm asking because
7 the symptoms you all are experiencing are so multisystem
8 and multidimensional. And so I'm wondering, I've heard
9 a few comments like, we'd be willing to try just about
10 anything at this point but then I've also heard some
11 comments that caveat that to say that something that
12 worsens another aspect of my long COVID that I'm dealing
13 with would be unacceptable. So I'm trying to get a
14 sense as to what, from your personal experience, what
15 would you be willing to tolerate as a side effect and
16 what would just be out of the scope of what you would be
17 willing to tolerate in a clinical trial.

18 MS. FISHER: Okay. From my personal
19 experience, I think because I did have a little bit more
20 of a severe acute case, I am willing to tolerate a
21 little bit more discomfort in managing pain things due
22 to a treatment. And if there is some type of historical
23 evidence that that would go away or dissipate within a
24 certain period of time, that gives me more incentive to
25 try it. I guess it's really nuanced, and it comes down

1 to those small quality of life measures. Is my GI
2 symptom going to be upset by this medication 15 percent
3 more five days a week or 10 percent more three days a
4 week? Those are the types of questions that I'm asking
5 when I'm considering treatments.

6 MS. BENT: Thank you. Let me turn to
7 Michelle.

8 MICHELLE W.: So in terms of being willing to
9 risk, I think one of the first questions I would have
10 is, is there treatment for these side effects? So let's
11 say something's going to make you potentially make you
12 really, really nauseous, but Zofran works really well to
13 stop the nausea. For example, my daughter does take a
14 medication that manages a symptom very, very well. The
15 side effect can be severe nausea in the beginning,
16 vomiting and other side effects. But we were able to
17 combat the side effects.

18 Also are the side effects reversible? So
19 let's say it does cause an elevated blood count or a
20 risk of infection, but after six months that's reversed
21 and you go back to baseline. That's more tolerable than
22 something, let's say, oh, it can cause increased liver
23 function values. And once they're elevated, they're
24 elevated. We've done treatment that actually did cause
25 severe side effects, DVTs, in fact. And it was a known

1 risk and we took the risk. Unfortunately, she had the
2 side effect and therefore had to stop. However, we
3 brainstormed and tried to figure out how to continue
4 trialing that treatment because it was working.

5 So if a treatment is working, the risks are
6 much more palatable, as well as knowing that there is
7 treatment or there's something we can do or after the
8 study, the chances are very high that any side effects
9 will be reversed. Also the opportunity, like we did
10 with the cognitive rehab, is knowing that if side
11 effects become intolerable, to leave the study. For my
12 daughter, intolerable meant that she was sleeping 20-
13 plus hours a day again. And we had managed that symptom
14 prior when she was at the point where she literally
15 could not be awake other than a couple of hours, we had
16 to drop out of the study. So risk/benefit ratio.

17 DR. KARIMI-SHAH: That's exactly what it comes
18 down to. Thank you for your answer.

19 MS. BENT: Thanks, Michelle. Let me turn to
20 Ryan and then we're going to turn to some callers to
21 hear some of their experiences. So Ryan, go ahead.
22 Thank you.

23 RYAN N.: So when I think for some of the
24 studies that are being mentioned that patients wouldn't
25 want to do, I think from what I've heard in patient

1 advocacy groups and stuff, a lot of them are related to
2 things that have been tried for ME/CFS already and don't
3 have strong support behind them. So I think for a lot
4 of the studies where people are saying, I wouldn't
5 really do this, I've been hearing it's been more like
6 exercise therapy or cognitive behavioral therapy.

7 So I think part of that for some of those
8 studies is that it's not necessarily just about the
9 worsening of symptoms, but also is there a large body of
10 research suggesting that this might not be an effective
11 treatment. So I think that's one thing to pay attention
12 to, if you're hearing patients saying, we don't want to
13 do this particular study, or something like that.

14 But as for me and my own risk tolerance, as I
15 mentioned, I've had long COVID for a year and a half.
16 I've not really been able to maintain a job, a normal
17 social life, the independence that I had before. So my
18 risk tolerance would be pretty high, especially for a
19 clinical trial. I be very much willing to deal with
20 side effects, knowing that they might dissipate if I go
21 off the trial or if my body has time to acclimate to
22 them.

23 I think the biggest thing that I would have
24 concerns about would be essentially the risk of
25 irreversible side effects or death or something like

1 that. For example, in anticoagulant therapy, I would
2 probably want to have some sort of test to see if
3 microclots are actually happening because going on
4 anticoagulants when you have normal blood might not be
5 like the best, and then that could cause like a stroke
6 or something irreversible. But overall, in terms of,
7 let's say, discomfort or reversible side effects,
8 especially for just a clinical trial, and that's
9 something that I'm not necessarily going to be on for
10 the rest of my life, yeah, my tolerance for that is very
11 high.

12 LARGE-GROUP FACILITATED DISCUSSION ON TOPIC 3

13 MS. BENT: Thanks, Ryan. Really appreciate
14 your thoughts on that. So with that, I think we're
15 going to give our panelists a little bit of a break and
16 we're going to turn to our callers, and I think we will
17 go first to Michelle on line seven.

18 Michelle, would you like to share with us some
19 of your thoughts and experiences related to clinical
20 trial participation? Maybe talk about what made it
21 easier or what made it harder?

22 MICHELLE: Yes. Hi. Thank you. Thank you
23 for having this meeting and for taking the time to
24 include patients and also hear the feedback and move
25 forward with some things. I have had long COVID for two

1 and a half years. I had my first COVID infection in
2 September 2020. My first infection was mild. One month
3 after I had that infection, I started having constant
4 chest pain. An ECG at my primary care revealed an
5 abnormal ECG. Before I could check into this more, I
6 got COVID again from a family member visiting us in
7 November of 2020.

8 The second infection about did me in. It was
9 so much worse. I had every symptom except a fever, and
10 my oxygen was above 90 percent when I went to the ER
11 urgent care. Of interest, my symptoms got better at
12 about three weeks before getting incredibly terrible at
13 four weeks after my second infection. I had elevated D-
14 dimer for months. I had the abnormal ECQ, which
15 persisted for over a year. I had collapsed veins. I
16 had bilateral ground glass opacities, and I had very low
17 white blood cell counts. But I'm in my 40s, early 40s,
18 and no one would do anything except just send me home
19 and say to stay hydrated.

20 Since then, I have done so many things to try
21 to get better. Every inch I can get. I very much want
22 to get better. I have tried and participated in two
23 long COVID trials, NIH trials. Part of what allowed me
24 to participate in these trials was the location and
25 accessibility. I think that those three things,

1 location, accessibility and visibility are really
2 important. It's my hope that there can be coordinated
3 locations to help reach people who want to participate
4 in these trials, but they're not near a main center like
5 the RECOVER Initiative. I'm not well enough to go fly
6 to New York or to places where I could participate. So
7 I think that that's really important, that there's
8 possibly a coordinated approach.

9 I also wanted to mention regarding one of the
10 panelists or the doctors had asked about toxicities and
11 side effects. One of the things that -- there was no
12 toxicities for either of the trials that I participated
13 in. So it was an easy yes, because one was virtual and
14 one was close by to me. If there was toxicities that
15 were being possible from a drug that was being trialed,
16 I think the thing that would affect me is could those
17 toxicities cause permanent damage because that would be
18 something that might turn me away, or if those
19 toxicities would just be short-term damage or would get
20 better once the drug was stopped, I would still consider
21 trialing a drug.

22 So the other thing is the Mind Body study. I
23 participated in a Mind body long COVID study. It was
24 based out of Beth Israel Deaconess. I'm based in
25 Milwaukee. So obviously this was a virtual study. It

1 did help me with some of my muscle pain. It was
2 accessible to me because it was virtual. Ideally,
3 studies that don't include a placebo are better for
4 patients, in my opinion, because everyone who has long
5 COVID right now wants a chance to get better as soon as
6 possible. Any studies are better than no studies. And
7 I know that the placebo studies are often more highly
8 regarded, but I think everybody so desperately wants to
9 have a chance to get better because we're trying so many
10 things on our own, and frankly, a lot of things aren't
11 working.

12 I did participate in a COVID probiotic study
13 on vascular effects at the Medical College of Wisconsin.
14 I was able to participate in this due to location. I
15 did receive the placebo, but I am trying the probiotic
16 on my own, out of my own cost afterwards to see if it
17 helps.

18 Ideal outcomes for me, studies would include
19 reduction in fatigue, brain fog, neurocognitive
20 dysfunction. One of the panelists mentioned misusing
21 words frequently. Yes, that happens all the time.
22 Difficulty focusing, where I had no difficulty focusing
23 before, I was a magna cum laude graduate. Very able to
24 focus and write a paper very effectively. I have
25 chronic circulation problems now and vascular problems.

1 I still have noncalcified nodules in my lungs, vision
2 problems, chest pain and breathing problems.

3 One thing that I'd like to add that I don't
4 think was mentioned yet is I had no known risk factors
5 before COVID that would have given me a heads-up that it
6 was going to be so bad for me. And so some trials with
7 specialized tests such as cytokine test, tomatine test,
8 immunological tests, genetic testing, biomarkers to help
9 understand more about what happened with me with COVID
10 and why me and so many of us got so ill and aren't
11 recovering. I would like to not just have a trial give
12 me treatments, but I'd also like to know why the heck
13 this has been so bad for me. I had no idea that it
14 would be.

15 MS. BENT: Right.

16 MICHELLE: Of note, the last thing I'd like to
17 add is that it is my hope that a drug like Evusheld,
18 which is a long acting monoclonal antibody which may
19 help with viral persistence, will be included as a
20 treatment based on my and a small amount of other long
21 COVID patients' positive experience. I received
22 Evusheld in 2022 for my new post-COVID immune-
23 compromised status because I had chronic low white blood
24 cell counts after COVID, and I did not have that problem
25 before. I found that Evusheld surprised me

1 dramatically. It helped with my long COVID fatigue,
2 lightheadedness and GI symptoms. It helped my fatigue
3 so much that I was able to even complete something like
4 mowing the lawn, which was just totally out of my realm
5 before that.

6 I'd also like and hope that other drugs can be
7 trialed and repurposed. At this point, to me,
8 exploration is really important and new things aren't
9 going to get discovered if they're not looked at and
10 tried at this point. So I hope that long COVID
11 treatments and medicines will be vigorously explored
12 with expedited results and widespread locations for
13 trials or coordinated locations to reach people in
14 different areas.

15 MS. BENT: Thank you. Thank you, Michelle.
16 Really, really appreciate your thoughts about that and
17 really appreciate the detail that you went into. Let me
18 turn now to Alice on line four.

19 Alice, I know you've been listening and I know
20 you've been on hold for a while. I really appreciate
21 your patience. Would you want to give us some thoughts
22 about clinical trial participation and maybe what would
23 be important for you?

24 ALICE: Yes. Hi. Thank you so much for
25 taking my call and also to the FDA for holding this

1 interactive meeting. For full disclosure, I am a
2 physician who's been in practice for over 20 years, but
3 I've also been very severely affected by long COVID
4 since early 2020.

5 My brief comment is about the
6 inclusion/exclusion criteria and outcomes measures for
7 planned trials. In my personal case, unfortunately,
8 SARS-CoV-2 caused documented organ damage in previously
9 healthy organs, including brain, where I had an anoxic
10 brain injury, COVID encephalopathy and a resulting TBI-
11 like brain illness, in my blood, where I had a
12 hypercoagulable state that had to be treated with
13 anticoagulation, immune system where I've had
14 dysregulation and impairment for about two years of the
15 disease, in my heart and cardiovascular system where
16 I've had several issues including clots in legs, lungs
17 and brain, in my GI system where I lost my gallbladder
18 and appendix seven weeks apart, in my liver and in my
19 kidneys, where I had as bad as stage three kidney
20 disease.

21 So some of these organ issues have improved or
22 reversed, but others are still present. So as a result,
23 I personally have not been a candidate for many of the
24 clinical trials that have been proposed and are ongoing.
25 I'll repeat, a healthcare professional with severe

1 health issues due to SARS-CoV-2, and I have not been a
2 candidate for many of the trials. The point is, long
3 COVID can be associated with organ damage for some
4 people, I suspect a larger population than we may
5 recognize now. Some of the organ impairment may be
6 fully detectable, like mine and your previous caller
7 that had brain aneurysms and other organ involvement may
8 not be apparent yet. And it's very possible due to the
9 lack of longitudinal data beyond three years that we
10 haven't appreciated the full extent of outcomes of this
11 condition in the long COVID community.

12 So for clinical trials, I'd like the FDA to
13 address not only palliative therapies for symptoms, but
14 also definitive ones targeting underlying causes. But
15 my main reason for calling in is to discuss
16 inclusion/exclusion criteria for trials. So I'd like to
17 ask the FDA to carefully consider inclusion of patients
18 with acceptable degrees of documented or suspected organ
19 damage. This would include patients who've been sick
20 for a number of years, who may be more likely to display
21 it as organ damage seems to appear over time.

22 And this recommendation may seem
23 counterintuitive for some clinical trials, especially
24 when testing interventions that have known potential
25 toxicities. But I really would recommend careful

1 consideration of including of patients with an
2 acceptable degree of organ impairment in all trials
3 where it's possible, just as we do in some other
4 multisystem conditions in the rheumatology space and
5 cancer.

6 And finally, for studying outcomes, in
7 addition to safety and efficacy of plan interventions,
8 I'd like to see trial endpoints include improvements in
9 organ dysfunction as well as prevention of organ
10 dysfunction in the future. That concludes my remarks.
11 Thank you so much.

12 MS. BENT: Thank you, Alice. Really, really
13 appreciate that. Let's take a brief break from callers.
14 Let me turn to Shannon to see, Shannon, do we have any
15 comments from the Web related to toxicities? I feel
16 like we were talking about that a little bit before. Do
17 we have any comments?

18 MS. SPARKLIN: Yes. Thank you, Robyn. We
19 have received several comments to the webcast regarding
20 the question about toxicities, and there's a range of
21 answers that patients are submitting. Some are noting
22 that they are not willing to accept any side effects
23 that would make them sicker than they already are, while
24 others are willing to accept any side effects or
25 toxicities because they feel like they are at rock

1 bottom right now.

2 A few comments. One comment that I'll read
3 states that something that takes away any last
4 functional aspects is something that they would not be
5 willing to tolerate. For example, they were given a
6 medicine that can cause tearing of tendons and they
7 began to develop bruising around their knees and
8 Achilles tendons in their ankles. They immediately
9 discontinued that medicine because losing the ability to
10 stand and walk, in addition to everything else that they
11 had already lost, would be an intolerable risk.

12 Another comment noted that they would
13 definitely not be willing to tolerate pain, headache,
14 nausea or organ damage. And finally, a last comment
15 noted some of the symptoms that they would be willing to
16 tolerate would include mild symptoms that can be
17 relieved through over-the-counter treatment. So that
18 would include indigestion, nausea, mild pain and low
19 level headaches, while other symptoms that they're not
20 willing to risk or tolerate would include worsening
21 brain fog where they would not be able to communicate
22 and any small decline in function.

23 They also noted that they've tried many
24 antidepressants that drastically worsen their function
25 to becoming bedbound. And once they tried another new

1 medicine two months ago and it caused digestive issues
2 but helped decrease their pain. Thank you.

3 MS. BENT: Thank you, Shannon. I know that
4 we're getting a lot of comments into the webinar and we
5 really appreciate those comments. Let me turn back to
6 the phone. I think we'll go to Trista on line two.

7 Trista, would you mind sharing your thoughts
8 about clinical trials?

9 TRISTA: Thank you.

10 MS. BENT: Thank you.

11 TRISTA: Yeah. I am entering month 38 of long
12 COVID. I was fit with a healthy lifestyle and no
13 preexisting condition when I was hospitalized three
14 times in March of 2020 in New York City, and when I
15 arrived at the overcrowded EE, I was already in sepsis
16 and experiencing my first what my chart called a cardiac
17 event. I was mistreated with the high dose
18 hydroxychloroquine and azithromycin five-day protocol.
19 I then had a neurological event which cannot be
20 evidenced on modern imaging scanning technology, which
21 caused me to lose my verbal fluency and ability to speak
22 for seven and a half months.

23 Since then diagnoses of POTS, ME/CFS,
24 hyperacusis, tinnitus, seizures, aphasia, PTSD,
25 cognitive decline and fragmenting, otherwise called this

1 silly minimizing term brain fog, depression, anxiety and
2 other things I can't remember because memory loss. My
3 improvement plateaued at the one-year point. And by the
4 18-month point, I began experiencing new and worsening
5 symptoms, even with some treatments having previously
6 helped.

7 Just researching and applying for
8 participation in clinical trials on my own through the
9 .gov website is extremely difficult cognitively. I tell
10 every specialist I see in person that I am willing and
11 interested in participating in clinical trials and they
12 all just send me to the website to DIY the process.

13 I have participated in one clinical trial at
14 significant personal financial cost, requiring personal
15 loans from friends to cover travel and accommodations as
16 it was in Southern California and I am based in
17 Brooklyn. I did experience temporary improvement in one
18 aspect of my symptomology, benefits which waned as both
19 felt by me and reflected in the tests conducted 30 days
20 after the end of the treatment period. Since then,
21 those improvements have disappeared altogether. I
22 cannot afford to continue that treatment protocol on my
23 own out of pocket.

24 This was a study of long COVID women
25 specifically and according to the lead science

1 researcher, there was not one participant whose
2 reproductive health and menses cycle had not been
3 significantly impacted by long COVID and also by the
4 bivalent vaccine. This was not the specific subject of
5 this trial, but a secondary discovery of data affirming
6 my own patient experience.

7 I firmly believe we need more studies specific
8 to the reproductive health in long COVID women. Whilst
9 in one study we cannot usually participate in another
10 clinical trial without interfering with both baseline
11 and treatment result data for that other trial. I am
12 disqualified from other trials due to any one or
13 combination of the ten prescription medications I am on
14 from my neurologist, cardiologist, psychologist,
15 pulmonologist, GP or pain management doctor, all
16 necessary due to COVID.

17 Also, I cannot participate in any trial that
18 includes graded exercise or the likelihood of worsening
19 my symptoms and putting at high risk of stroke, heart
20 attack and increased seizure-like activity I got from
21 COVID, and many of the eligibility requirements are for
22 patients who have had a COVID positive test within the
23 past year only, leaving those of us in the first wave
24 infected behind.

25 I want my body's data to inform medical

1 interventions through participation in as many clinical
2 trials as possible. But I don't have the privileges of
3 financial wealth, nor help in daily life activities or
4 the cognitive efforts of self-tracking and recording my
5 responses to the treatment. The lack of accessibility
6 is a significant barrier and I agree that quality of
7 life, independent functioning and daily activities and
8 an improved life expectancy are important outcome
9 metrics to prioritize.

10 In terms of the risk of toxicity, we're
11 already on the edge of death, so frankly, anything not
12 already proven to kill me immediately, I would try.

13 MS. BENT: Thank you. Really, really
14 appreciate that feedback. Let me turn to Rachel on line
15 one.

16 RACHEL: Hello?

17 MS. BENT: Hi, Rachel. I know that you've
18 been waiting for quite a while. I know we all would
19 really want to hear your perspectives on clinical trial
20 participation. I would ask that you keep it as concise
21 as possible just so that we can get to maybe one more
22 caller before we are wrapping up the meeting. Thank you
23 so much for calling in.

24 RACHEL: Of course. Thank you. Hi. This is
25 Rachel. I have had long haul COVID since December 2020.

1 There are lots of types of long COVID. I have several
2 of them, but the one I'm going to talk about right now
3 is ME/CFS. A year ago I was too exhausted to feed
4 myself. It was before my CFS diagnosis. I lost 20
5 pounds in ten days because I couldn't move well enough
6 to feed myself. It's very hard to access treatment and
7 I'm really lucky that I've been able to.

8 I'm going to ask for two things today. One is
9 that I ask that consideration of trial designs look at
10 treatment for conditions seen in long COVID and other
11 post-infection conditions, things like what I have,
12 ME/CFS and POTS, that would enroll anyone with a
13 condition regardless of the trigger, whether it was
14 COVID or not. These are existing communities of
15 patients and we need to learn from them. I need to
16 learn from them.

17 I am very, very lucky and very privileged to
18 have access through a long COVID clinic to an ME/CFS
19 clinic. Last summer, I started low-dose naltrexone and
20 it immediately significantly improved me. I was stage
21 five and went to stage four fairly quickly, which meant
22 that I was no longer bedbound. Not being bedbound is
23 awesome. I also started low-dose Abilify last fall and
24 I'm 80 percent back to whole. And there are no active
25 clinical trials looking at these conditions, these

1 medications, and none looking at them in combination
2 either.

3 We need government funding for clinical trials
4 on these medications because for some people they can
5 create a significant improvement and these aren't going
6 to be highly profitable things to drug companies. So we
7 need federal support to be able to do this.

8 I have been asked to participate in a number
9 of clinical trials, as many other callers have echoed.
10 Some of us are desperate and terrified, while exhausted.
11 We will do a lot to participate in our care and to
12 participate in furthering the knowledge in the field.
13 And I've declined clinical trials because of the
14 economic precariousness that has been introduced into my
15 life because of long COVID.

16 There was one clinical trial that sounded
17 great. I would effectively be subsidizing it because
18 the small stipend didn't even cover the cost of gas. So
19 I'm willing to put a lot in. But many of us are now
20 experiencing a lot of economic precarity because of our
21 conditions.

22 And then when clinical trial results are
23 available, I have had to be far too strong of my own
24 patient advocate to be able to just stay alive and get
25 out of being bedbound. We need a different flavor of

1 outreach, one that's more rapid and more thorough once
2 clinical trial results are out so that more and more
3 medical professionals can be aware of the news of the
4 developing field.

5 And the last thing I want to say is that it's
6 really important the clinical trials look at the effect
7 of treatment on people who represent the full complexity
8 and the full diversity of the large long COVID
9 community. Lots of us have preexisting chronic illness
10 or disability, looking at the frequency of people with
11 autoimmune and complex chronic conditions. Clinical
12 trials need to take into account the diversity of
13 participants and put extra effort into that. Thank you.

14 MS. BENT: Thank you, Rachel. So we have just
15 13 minutes left of the meeting. I'm going to turn to
16 our final caller, Jillian, on line three. We're then
17 going to turn to Shannon for a wrap-up of the comments
18 that we've received on the website and then to closing
19 remarks. So I thank you all. We have about now 12
20 minutes left, and so let me turn to Jillian. I know
21 you've been on hold for a long time, so I really
22 appreciate that and please go ahead.

23 JILLIAN: Oh, my gosh, thank you. I was just
24 going to write you my stuff, so I wasn't sure what I was
25 doing. Okay. Thank you so much for holding this, to

1 the FDA for today's program. I've had long COVID for
2 three years, healthy, athletic, no preexisting
3 conditions in NYC. Now I'm disabled and on SSDI, living
4 with my mom. I'm in a 50-person independent research
5 group of science-minded long haulers, so I hope that
6 some of my comments represent some of their thoughts as
7 well.

8 The focus of this panel is trials, not
9 studies. So I was going to say I hope we can steer away
10 from RECOVER as a topic, given it's a study, and I
11 direct you to the recent Stat article detailing many of
12 its serious failings and need for reform. The
13 treatments that have been mentioned today are Band-Aids,
14 and I hope that trials will focus on cures.

15 I would also note that from a previous
16 caller's remarks, PTSD is not holding me back from
17 getting better. This is a physical, progressive
18 disease. We need trials for viral persistence for a
19 cure yesterday. Viral persistence has been largely
20 proven already. There are trials and studies that could
21 be done with cats for FIP, feline infectious
22 peritonitis, for example, which is a similar
23 coronavirus. I urge the government to explore this, as
24 there's already much evidence and research there.

25 For humans, there are several antiviral

1 possibilities to trial that the research community is
2 aware of. We need a variety of extended trial and
3 titration times. Fifteen days of Paxlovid isn't going
4 to cure people. We already know that. These, quote,
5 trials seem disingenuous at best. Emphasizing Liza and
6 Lisa's opening remarks, many of us do need logistical
7 help to participate, and in response to Dr. Karimi-
8 Shah's question on toxicity, and similar to many
9 panelists' replies, while I wouldn't want to experience
10 permanent or irreversible damage from a trial,
11 otherwise, my symptom threshold is high and I'm
12 comfortable taking risks given my desperation.

13 Echoing others' comments as well, placebo
14 studies seem like a waste of time given the urgency of
15 this crisis. And lastly, we need people -- to let in
16 people who got COVID before PCR tests because we make up
17 a huge number of the population of patients.

18 There are several other treatment options that
19 my group has been looking at that we care very much
20 about and think are serious contenders for symptom
21 improvement, such as cerebrylysin and other peptides
22 with proven safety and tolerability, such as ARA 290,
23 BPC 157, ANI third for people which seems to have
24 potential for MCAS, SS-31 for mitochondrial dysfunction.
25 I'd also note piracetam. The fact that this isn't

1 available as a drug for people with cognitive issues is
2 almost criminal. It's been around since the '80s and
3 it's about time that it has a trial to make it
4 available.

5 Drugs that target the immunomodulating factors
6 associated with damaged GABA receptors is prevalent in
7 people with long COVID. That's another one. Anti-
8 inflammatory drugs that lower IL1Ab and IL6 is very
9 important.

10 Drugs that address decoupled protein receptors
11 such as CC 007, which is currently being trialed in
12 Germany, why is the United States not doing that?
13 Trials that could potentially address what we see in
14 publications referred to as persistent spikes or
15 partially replicating spikes is also important,
16 especially if this is playing a role in driving systemic
17 inflammation.

18 MS. BENT: Jillian, I'm going to ask you to --
19 I need to ask you to maybe focus on maybe one more
20 topic.

21 JILLIAN: Sure. I'll close. Yeah, I'll close
22 by saying that Pilates, GET, CBT and mindfulness are not
23 going to cure us and in fact, these trials will hurt us
24 and spin a false narrative about long COVID. We already
25 know this from decades of destructive research for

1 ME/CFS, multiple sclerosis, et cetera. And lastly, I
2 would warn the meeting administrators of special
3 interest groups like the insurance industry pushing
4 their own agendas and skewing your data. Thank you so
5 much.

6 MS. BENT: Thank you, Jillian. And thank all
7 of you. To those of you who we weren't able to get to
8 on the phones today, I really do apologize. Please,
9 please consider submitting your comments to the public
10 docket because your thoughts are important to us.

11 Now I'd like to turn to Shannon to share maybe
12 some final comments that we received via the Web before
13 turning over to Rear Admiral Iademarco to provide
14 closing remarks. So Shannon, please, go ahead.

15 MS. SPARKLIN: Thank you, Robyn. Just to
16 mention, the perspectives that have been shared today
17 that maybe we haven't been able to get to will be
18 reviewed and incorporated into the meeting summary
19 report.

20 But regarding some of the themes I've been
21 seeing in the written comments related to clinical
22 trials, some themes have been that it's difficult to
23 access trials, especially for rural populations, and
24 that there is a desire for virtual trials or less clinic
25 visits. There's also been a key theme regarding

1 inclusion criteria to make clinical trials more
2 accessible to people with preexisting conditions and
3 specific symptoms of long COVID.

4 A few important outcomes that people who
5 submitted comments mentioned are reduction of fatigue,
6 reduction of post-exertional malaise and reduction in
7 brain fog.

8 One thing that a commenter noted would
9 facilitate their participation in a trial would be
10 location, time commitment, and out of pocket costs. And
11 that same commenter noted that if something ends up
12 being only 5 percent impactful, that is a huge
13 improvement for them.

14 One commenter noted the factors that enabled
15 them to participate in a clinical trial included
16 reimbursement for transportation costs, the fact that
17 the trial was close by, low physical and mental effort
18 and the factors that made it more difficult for them to
19 participate included the trials that focused on exercise
20 or physical activity that made their symptoms worse and
21 where the study locations were hard to get to or
22 expensive.

23 Finally, another comment mentioned that many
24 long COVID patients are presenting as immunocompromised
25 or with immune dysfunction. However, many settings,

1 including hospitals, have dropped mask mandates, and
2 this has made participating in clinical trials
3 significantly more dangerous for these patients,
4 particularly as they see how reinfection is associated
5 with increased risk and worsening of symptoms. And they
6 would appreciate mask hearing in hospitals and
7 telehealth or virtual options to limit this risk for
8 long COVID patients who are choosing to participate in
9 trials. Thank you.

10 MS. BENT: Thank you, Shannon, for, as always,
11 providing a very comprehensive overview of the comments
12 that we've received. So before I turn the microphone
13 over to Rear Admiral Iademarco, I just do want to
14 acknowledge that this was a very long meeting. And we
15 understand that for those of you who are suffering from
16 long COVID, particularly with the aspects of fatigue and
17 post-exertional malaise, this meeting was a lot for you.
18 And we very much appreciate you taking the time to
19 participate and share your experiences with us. They
20 are very meaningful.

21 And so with that, I am happy to turn over to
22 re Admiral Iademarco, the deputy assistant secretary for
23 science and medicine at the U.S. Department of Health
24 and Human Services, who will be kind enough to provide
25 us with closing remarks. Admiral?

1 CLOSING REMARKS

2 DR. IADEMARCO: Okay. Good afternoon. Just
3 want to make sure the sound check is okay. I haven't
4 spoken for a couple of hours.

5 MS. BENT: Yes. We can hear you, sir.

6 DR. IADEMARCO: Okay. Good. Well, I want to
7 thank everyone, and there's no particular order. Doing
8 this is hard, and I've been in biomedical science and
9 public health for several decades, and I think we're
10 getting better at it. But it's still a learning
11 process. And I want to applaud the FDA and all the
12 participants for working together for a very respectful,
13 constructive exchange. And it's not comprehensive, it's
14 not complete, and it's not perfect, but I think it was
15 done extremely well.

16 FDA, in their opening comments, explained
17 their evolving journey in this methodology. And of
18 course, we all applaud that and encourage them forward.
19 And I know firsthand how this information fits together
20 with what everyone's trying to do, and that is to
21 improve the outcome of patients with long COVID and
22 associated conditions.

23 I want to also note, I don't know if we
24 mentioned this earlier, that there were people from the
25 CDC and the NIH on the call listening firsthand. And of

1 course, there'll be notes and recordings as described
2 that will help those scientists. And it really is an
3 all of government approach, not just within NIH with the
4 different organizations, the two I just mentioned with
5 the FDA, but others, such as the VA and the DoD, who are
6 doing research in this area. And then there's other
7 smaller groups in HHS where this is very relevant,
8 whether it be ARC, URSA, ACL, et cetera, and CMS for
9 their role with insurance, for example.

10 There's been a lot of diversity and views here
11 and in the people speaking, and you can just tell by any
12 one person listening that it's a lot to pull together,
13 that diversity is rich and robust and really important,
14 but at the end of the day, we have to pull it together
15 and make some steps forward in the right direction. And
16 we may not always get it perfectly right, but that's
17 what we're aspiring to do in HHS.

18 If you have suggestions on the process or the
19 method that FDA used here, I'm sure they're all ears to
20 that and there's various ways to respond. I'm looking
21 through my notes here to make sure I hit everything I
22 thought of. And I think so, so I'm really appreciative
23 of all this, everyone's time. I learned myself
24 listening to all the stories of the various patients and
25 caregivers. So thank you. Shannon, back to you.

1 MS. BENT: Great. So thank you. I'm going to
2 jump in again. So thank you, everyone. I hope that you
3 have a wonderful day. I would like to just take this
4 opportunity to thank all of the staff that put this
5 together, all of the people working on the backend, our
6 interpreters, our studio staff and all of the rest, but
7 of course, most importantly, the patients who were
8 really here to share their experiences. So thank you
9 all, and have a wonderful day.

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(Whereupon, the foregoing was concluded.)

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2 I, RICHARD LIVENGOOD, the officer before whom
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